Alberta Heritage Foundation
for Medical Research

Patient Diabetes Education in the Management of Adult Type 2 Diabetes

Paula Corabian and Christa Harstall

February 2001

HTA 23: Series A

Patient Diabetes Education in the Management of Adult Type 2 Diabetes

Paula Corabian and Christa Harstall

February 2001

This Health Technology Assessment Report has been prepared on the basis of available information of which the Foundation is aware from public literature and expert opinion and attempts to be current to the date of publication. It has been externally reviewed. Additional information and comments relative to the report are welcome and should be sent to:

Director, Health Technology Assessment
Alberta Heritage Foundation for Medical Research
3125 Manulife Place, 10180 - 101 Street
Edmonton, Alberta T5J 3S4
CANADA

Tel: 780-423-5727, Fax: 780-429-3509

ISBN 1-896956-39-4

Alberta's Health Technology Assessment program has been established under the Health Research Collaboration Agreement between the Alberta Heritage Foundation for Medical Research and the Alberta Health Ministry.

ACKNOWLEDGMENTS

The Alberta Heritage Foundation for Medical Research is most grateful to the following persons for their comments on the draft report and for provision of information.

Ms. Peggy Dunbar, Coordinator, Diabetes Care Program of Nova Scotia, Halifax, Nova Scotia

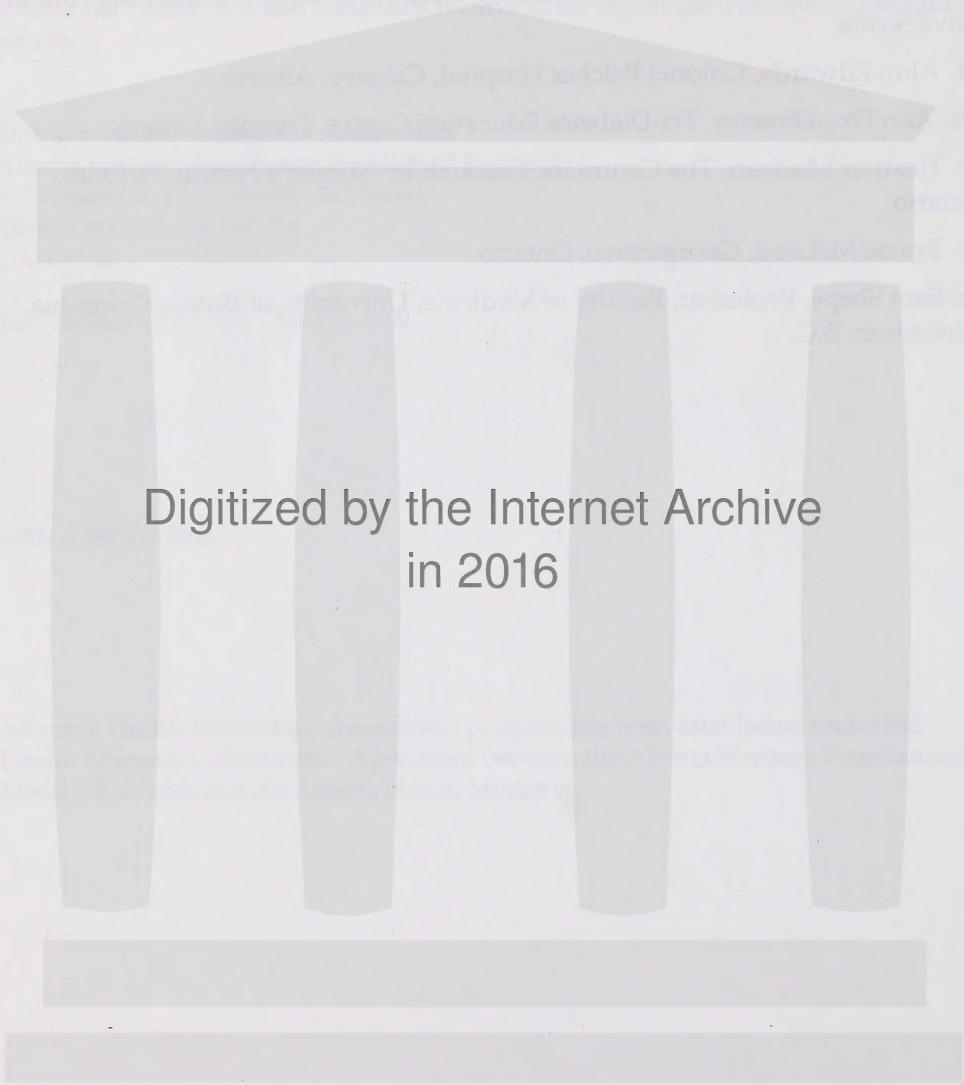
Dr. Alun Edwards, Colonel Belcher Hospital, Calgary, Alberta

Ms. Ann Fox, Director, Tri-Diabetes Education Centre, Toronto, Ontario

Dr. Heather Maclean, The Centre for Research in Women's Health, Toronto, Ontario

Dr. Brucie McLeod, Georgetown, Ontario

Dr. Sam Sheps, Professor, Faculty of Medicine, University of British Columbia, Vancouver, B.C.



SUMMARY

- Formal patient education in diabetes self-management (referred to here as patient diabetes education or PDE) at different levels of complexity and comprehensiveness, has emerged from instruction by physicians, nurses, and dieticians in physician's offices and hospitals.
- The past decade witnessed a shift from traditional approaches of PDE to a focus on patient-centered perspectives, self-efficacy, and empowerment issues.
- The published reports on the effectiveness of PDE as a tool to promote self-management in adults with type 2 diabetes produced mixed results in terms of improved metabolic control and reduced risks for diabetes-associated complications in the long-term. The results are not directly comparable since investigators have used different designs, PDE programs, patient populations, sample sizes, follow-up periods, types of outcome and outcome measures. Also, the inadequate data presentation limited the interpretation of the available evidence.
- The long-term diabetes control outcomes of formal PDE when used to promote self-management in adults with type 2 diabetes have yet to be defined and appropriate measures established.
- The available evidence did not permit to draw reliable conclusions on:
  - which types of programs or what components are most effective in improving the ability of adults with type 2 diabetes to self-manage their disease; or
  - which category of patients might benefit most.
- This review confirmed results of previous ones:
  - there is no consistent pattern of effect across outcomes based on type of intervention, length of educational intervention, core team composition or type of educational setting; and
  - there is no standard method to describe formal PDE programs and interventions, thus making it difficult to replicate studies.
- Findings from qualitative research studies were useful in illuminating the findings from quantitative research studies, by helping to understand better the context in which formal PDE should be applied to be successful in promoting self-management behaviors in adults with type 2 diabetes.

- The administrators of formal PDE programs need to consider that the trends in formal PDE delivery call for:
  - an ongoing patient-centered PDE approach, described as a step-by-step process which involves the diabetes care and education providers, the patients and their caregivers;
  - focus on meeting the patient's needs and overcoming patient's barriers to self-management behaviors, and continuous reinforcement of patient's positive behaviors, besides transmission of knowledge and skills;
  - the development of trustful patient-educator relationships and the existence of good partnership with the other members of the diabetes management team;
  - measurement of PDE success in terms of both long-term outcomes and short-term outcomes, regardless of PDE approach.
  - data collected for each outcome by using a more standardized set of validated instruments.
- None of the Canadian studies published over the last ten years met the criteria in the working definitions and inclusion criteria for review. Canadian investigators can build upon the research described in this report and should attempt to overcome the methodological limitations of the reviewed studies.

CONTENTS

SECTION 3:

APPENDIXES:

TABLES:

INTRODUCTION

This report is a systematic review and critical appraisal of the literature on the use of formal outpatient diabetes education as a therapeutic tool for self-management in adult patients with type 2 diabetes. It has been prepared to provide information to the Capital Health Authority in Alberta, Canada and to others on the available published evidence on the efficacy/effectiveness of the existing education programs in terms of long-term patient outcomes. The aim was to provide the current evidence to guide recommendations regarding which program formats may be most effective in helping adult patients with type 2 diabetes achieve diabetes control in the long term.

Diabetes is a chronic and potentially disabling metabolic disease for which there is no cure. With diabetes the body fails to produce enough insulin (a hormone released by the pancreas that helps the body to convert the blood-glucose into energy) or fails to respond properly to insulin. It is a heterogeneous disease crudely grouped into two main forms: type 1 (also known as insulin dependent diabetes mellitus or IDDM) and type 2 (also known as non-insulin dependent diabetes mellitus or NIDDM). Differentiation between these two forms is sometimes difficult because of a wide range of insulin dependence patterns [9]. Although some worldwide consensus on the diagnosis and classification of diabetes has been achieved, the standards are still debated [9, 16, 91].

Diabetes is one of the most common metabolic diseases in all populations and all age groups worldwide [16]. Recent epidemiological data suggest a growing incidence and prevalence of both type 1 and type 2 diabetes and it is predicted that by the year 2010 the number of people suffering from diabetes will double the estimated 110 million worldwide in 1994 [62]. Most of the increase will be in type 2 diabetes, currently the most prevalent kind of diabetes, accounting for 85%-95%of all cases [1,9,24,55]. In Canada, the number of individuals aged 12 years and over with diabetes has been estimated at 1.2 to 1.4 million (4.9% to 5.8% of the population aged >12 years) [55].

Type 2 diabetes is characterized by a scarcity of signs and symptoms and often referred to as mild diabetes. However, it is among the commonest causes of blindness in adults, an important cause of renal failure resulting in need for dialysis, and the most common condition leading to lower limb amputation [24, 25, 44, 55]. In addition, people with type 2 diabetes have an increased risk of myocardial infarction or stroke and are more prone to clinical depression [1, 22, 77].

It is generally believed, and implied from the results of United Kingdom Prospective Diabetes Study, that to prevent/delay diabetes-related complications, patients with type 2 diabetes should maintain glucose levels as close as possible to non-diabetes levels and work towards reducing cardio-vascular risk factors [6, 28, 77, 88, 100-102, 105]. Patient education in diabetes self-

management has emerged as a therapeutic tool to help patients understand and self-manage diabetes and hopefully become active participants in their diabetes care. It has the task of teaching the intricacies of the complex balance of medications, diet, exercise, and lifestyle changes involved in diabetes self-management as well as updating diabetes knowledge and technology. Over the years it evolved to the point where it is now considered as an integral component of comprehensive diabetes management. [26, 40, 62, 90].

SCOPE OF THE REPORT

Approaches to effective educational interventions have been the source of a great deal of study and discussions. This report is not intended as a comprehensive review of all educational interventions used for patient education in diabetes self-management, referred to in this paper as patient diabetes education (PDE).

Rather, this assessment has been focused on appraising the published literature on formalized or formal PDE (see working definitions in Appendix A) because of the interest and debate regarding the use of formal PDE delivered as outpatient programs in Alberta. A preliminary review of the literature revealed that a variety of formal PDE of different levels of complexity and sophistication have been developed and used to teach self-management in adult patients with type 2 diabetes.

Given the mixed results from the published literature on the impact of these interventions on diabetes control in terms of long-term patient outcomes a systematic review of the relevant published primary and secondary research studies has been undertaken. Because many changes in diabetes education and care occurred in the late '80s and early '90s, the review considered only the literature published from 1990 to March 2000. The aim has been to respond to the questions: "what kind of formal PDE program delivered in outpatient settings is most effective in the long term, for what category of patients and under what circumstances". Consequently, for the purpose of this review it was decided to focus on PDE interventions or programs matching the working definition (see Appendix A).

The questions on whether PDE influences self-management behavioral changes in the long-term or on how to maintain these changes once made still do not have clear answers. Consequently, for the purpose of this review, it was decided that success of PDE would be determined by studies that reported results on the therapeutic effects of PDE over a minimum of 1 year period on clinical, cognitive, psychomotor and affective domains of the diabetes self-management. The methodological approach used for this review is outlined in detail in Appendix A.

This report consists of three sections. The first section presents a review of the recent primary and secondary quantitative research providing evidence on the efficacy of formal outpatient PDE for improved self-management in adults with type 2 diabetes. A critical appraisal of the relevant primary quantitative studies (controlled or comparative) and meta analyses is included. The criteria used to determine the methodological quality of the reviewed studies is outlined in Appendix B. This section also identifies the studies on formal PDE conducted in Canada over the last 10 years.

The second section of the report summarizes the information on the bio-psycho-social context of and barriers to diabetes self-management and their potential influence on PDE success on long-term diabetes control. To better understand what the research tells us about the attributes of programs that may enhance the effectiveness of formal PDE a summary of the findings reported by qualitative research studies that addressed the context of and barriers to diabetes-self-management is included. A discussion on the methodological quality of the reviewed qualitative research studies is presented in Appendix H.

The third section discusses the findings of this technology assessment and presents the conclusions.

SECTION 1

FORMAL PATIENT DIABETES EDUCATION

Evolution

Since the early 1920s patient education has been proposed as an essential therapeutic tool for diabetes management and has emerged as an integral component of comprehensive diabetes care during the last 50 years [4, 26, 34, 40, 64]. It has evolved from instruction by physicians, nurses, and dieticians in physician's offices and hospitals to more formal and comprehensive patient diabetes education programs [26]. Traditionally, the content of formal patient diabetes education (referred to here as patient diabetes education or PDE), whether provided in individual or group sessions, is determined by what the educator considers to be the most appropriate. It provides information mainly related to diabetes and self-management skills, with occasional attention paid to psychosocial concerns and behavioral change [12, 32, 43, 76, 82, 87].

During the last decade, the PDE approach and delivery have changed, partly reflecting the increased concern for greater effectiveness by improved motivation of both patients and providers. Many changes have occurred as a result of recent technological advances in the management and care of diabetes. New knowledge about the importance of metabolic control, discovery of newer and better therapies, and improvements in the technology for monitoring and measuring glucose level have raised hopes that patients can attain greater levels of independence and self-management [67, 83, 87]. At the same time, the theory and research base for PDE has expanded and its value and role have gained recognition [67]. Standards for PDE and certification for diabetes educators have been developed and implemented [24, 32, 39, 67].

A growing sense of dissatisfaction has been observed among both patients and providers with the use of the traditional approach to PDE along with an increased awareness of a need for programs that are adequate to deal with the complexities of living with diabetes [4, 15, 34, 38, 39, 71, 76, 83, 87]. Increased recognition of the influence of psychosocial and environmental issues on patient's behavior, has led some investigators to consider that the biomedical model of information transfer may be inadequate to support educational techniques which are needed to influence patients' behavior change [12, 26, 34, 39, 50, 64, 87, 99].

The focus of the PDE approach has changed from compliance to adherence to self-efficacy and empowerment. The power of the patient-provider/educator interaction shifted from the provider/educator to the patient [4, 15, 33, 34, 39, 43, 50, 58, 60, 63, 67, 75, 76, 87, 96]. Also, the focus of responsibility for non-compliance and poor adherence has shifted away from the patient alone to a shared responsibility with providers of diabetes care and education and the consideration of the quality of the interaction with the providers [33, 34, 87].

It has been suggested that the ability and readiness of patients to learn is dependent on their needs and personal beliefs and that educational messages are meaningful only when the person who hears them is ready and willing to learn [8, 21, 50, 67, 75, 83]. The person with diabetes is the only one in a position to determine what is learned and what is ultimately practiced [3].

Theories of learning and behavior

Various theories of learning and behavior including strategies to increase compliance and adherence have been tested and reported in the literature. Examples of these include the health belief model, the socio-behavioral model, self-efficacy and empowerment [12, 13, 50, 58, 63, 67, 96] . Although to date these theories have had limited testing [13, 27, 67, 73], they have increased the knowledge base on mechanisms by which the patient's psychosocial and environmental context affects his/her acceptance, compliance and adherence to regimens, which may alter short- and long-term diabetes outcomes. They also provide guidance for investigators in their efforts to develop PDE approaches to fit better with human behavior. This would allow improved compliance and regimen adherence and consequently long-term diabetes control.

One of the theories frequently advocated in the literature as a useful model for PDE is patient empowerment. It has been suggested as a new approach for PDE, in order to cope with rapidly changing patterns of diabetes care and management, and to integrate its clinical, psychosocial and behavioral components and self-management education. This approach recognizes the nature of the actual experience of having diabetes and views the health care professional as a resource person/consultant [4, 6, 15, 21, 27, 34, 39, 50, 60, 64, 67, 83, 87]. The purpose is to provide a combination of diabetes knowledge and self-management skills, and heightened self-awareness regarding values, beliefs, needs, and goals so that patients can use this power to make informed decisions about their behaviors and act for their self-care. The more traditional definition views PDE as a process designed to influence the knowledge, attitudes and behavior of patients to enhance compliance with treatment recommendations in order to improve their diabetes control.

Advocates believe that empowering patients to effect behavioral change has the potential to change overall health status and to expand resources into other personal and social areas [4, 15, 21, 39, 60, 87]. PDE designed to empower patients to self-manage diabetes in the bio-psychosocial context has a very different goal than PDE designed simply to persuade patients to comply with the treatment recommendations of health care providers in order to improve their health status [15, 39, 50, 87]. To empower, the PDE approach needs to be adapted to meet patient's needs, and to reflect and express his/her lived experience with diabetes through recognition and promotion of individual strengths, informed choices, and personal goals [4, 6, 15, 39, 60, 64, 67, 83, 87].

It has been increasingly recognized that improved diabetes knowledge alone is not necessarily sufficient to initiate and maintain self-care behaviors and to ensure long-term diabetes control [15, 50, 58, 64, 76, 87]. As a result, some PDE programs have been designed to address stress, psychological well-being, attitudes, motivation, coping styles, social support, health locus of control, self-efficacy and/or health beliefs. These programs supplement traditional didactic instruction on the patho-physiology and medical treatment of diabetes with individualized attention to the particulars of self-management to help patients change elements of their lifestyle behaviors [34, 73, 79].

PDE programs

The PDE program's main goal is to promote self-management that in turn may lead to long-term diabetes control to reduce associated morbidity and mortality, increase patients' quality of life (QOL), and reduce costs [6, 28, 77, 100-102, 105]. Its success should be measured in terms of both long-term and short-term outcomes. The program produces short-term outcomes, which act as the stepping-stones to the desired long-term outcomes. The short-term outcomes should include improved glucose control, and reduction of cardio-vascular risk factors presence (such as obesity, hypertension, smoking and high blood lipid levels).

Participants attending a PDE program presumably change through improvement in underlying process or mediating variables such as knowledge, attitudes, self-efficacy or sense of control, health beliefs, health locus of control, personal models, problem solving, coping skills, intentions, motivation, and social support. These changes are then translated into improvements in one or more areas of diabetes self-management behavior including changes in lifestyle and medical self-care and monitoring and/or in one or more areas of diabetes management (associated with the patient-provider interaction).

There is still a lack of consensus on which are the most relevant measures of PDE success or failure in terms of diabetes outcomes [11, 15, 26, 47, 50, 64, 65, 67, 71, 73, 87]. Some argue that metabolic control and morbidity are the important outcomes to measure. Others argue that changes in attitudes, QOL, and adherence to self-management behaviors are more proximal outcomes because metabolic control and morbidity are mediated by a number of other factors that PDE cannot be expected to affect directly. Both QOL and adherence were identified as variables that are difficult to measure quantitatively [67].

The role of diabetes educators has been assumed by various health care professionals, including nurses, dietitians, physicians, chiropodists, pharmacists, psychologists, mental health professionals, and social workers in multi-professional teams or alone [4, 8, 23, 33, 53, 58, 67, 83]. Some investigators view diabetes educators as "self-care professionals" who have to master knowledge and skills in the biological and social sciences, communication, counseling and

education, and who have to have experience in the care of patients with diabetes [4, 58].

Computerized PDE interventions may lead to improved diabetes outcomes and appear not to be a substitute for, but a valuable supplement to human interaction [29, 34, 46, 61, 81]. Many clinics have used computer-based instructions, with either direct system-patient interaction or an intermediate operator [64]. The application of computers to diabetes management has expanded to include assessment of knowledge and behavioral change. It also includes calculating insulin dosage or dietary requirements (by using a variety of software programs), storage and analysis of diabetes management data and instruction and simulation in a variety diabetes-related tasks for patients and providers [29, 34, 46, 81].

AVAILABLE EVIDENCE ON THE EFFECTIVENESS OF FORMAL PDE

Meta analyses

Four meta analysis studies which specifically focus on determining the effect of diabetic education programs were retrieved [18-20, 79]. Three of these studies were published by Brown and two of the studies were either updates or further refinements of a previous meta analysis study. Two of Brown's studies [19, 20] and one by Padgett et al. [79] are presented in detail in Table 1 (Appendix C). They are critically appraised using specific criteria (see Appendix B) that are intended for evaluating systematic reviews. Even though the study by Padgett and colleagues was published before 1990, this study was included. It presents a summary of findings of all studies published from 1976 onwards to 1986, which is similar to Brown's two meta analyses that include available studies from 1966 to 1989. Including the study by Padgett et al. allows for some comparative comments regarding the results from the meta analyses outlined in Table 1.

The main finding from all the meta analyses in Table 1 was similar in that patient education in the management of diabetes care is effective in producing beneficial outcomes. Padgett and colleagues' [79] meta analysis included a larger array of studies. They included a total of 94 studies of experimental design in which:

- PDE was provided in either an outpatient or inpatient setting;
- the sample size ranged from 5 to 859 subjects (average sample size 79) with an average age of 38 years;
- 20 studies were conducted with children and adolescents;
- only 14 studies followed up beyond the first post test outcome period;
- 45 studies included patients with IDDM and 25 studies only included patients with NIDDM; and
- 71 studies used only metabolic outcome measures (HbA1c and blood glucose levels).

The quality scores for the studies ranged from 2 to 14 out of a possible total score of 16 (average 7.5). Both the methodological quality and the study design were inversely associated with effect size. They observed that independent of outcome measures reported, the effectiveness of PDE decreases with time.

Brown [19, 20] was more selective in the studies that were included in her two meta analyses detailed in Table 1. Further to the inclusion criteria used by Padgett and colleagues, Brown included only studies on adults and if the setting for PDE was the same for both the control and treatment groups. Brown also included unpublished studies. In the 1990 meta analysis [19] of 82 studies, 32% of these studies were unpublished. The majority of the studies included in the meta analyses were published since 1981. However, 39% of all of the studies in the

meta analyses combined the outcome results of patients with type 1 and 2 diabetes. Fifty-six of the studies used control groups and the quality score ranged from 5 to 18 (average 11.5 ± 3.29) out of a maximum score of 21. Brown found a statistically significant relationship of study characteristics (publication date, attrition rate, quality rating, length of program between intervention and outcome measure), and age using correlation analysis.

The meta analysis published in 1992 by Brown [20] used the same studies but excluded studies that measured only blood glucose levels rather than HbA1c. This reduced the number of studies included in the meta analysis from 82 to 73. The intent of this meta analysis was to determine the influence of study characteristics, such as quality, and subject characteristics, such as age, on outcome measures. The following summarizes the findings:

- studies of less rigorous design and unpublished studies showed a larger effect size;
- higher quality studies produced a larger effect size for weight loss and a smaller effect size for HbA1c;
- inpatient PDE programs produced a larger effect size for knowledge and metabolic control and outpatient PDE programs showed a larger effect size for weight loss and skill performance;
- the longer the duration of PDE programs over a period of time the larger the effect size of knowledge and skill performance, however HbA1c did not differ with respect to duration;
- based on the length of follow up, effect size of PDE on skill and knowledge performance increased over time to at least 1 year while degree of weight loss decreased to lower levels;
- PDE had an early moderate effect size on HbA1c levels with a peak at 1 to 6 months followed by a decline to earlier levels after 6 months; the effect of PDE on psychological outcomes was the opposite;
- effect size of PDE on knowledge and for HbA1c levels for patients over the age of 40 years is smaller than for younger patients.

Brown [20] found that age influenced the magnitude of effects for most outcomes. She also reported that the educational setting did not affect outcomes consistently. Patients who were treated with insulin learned more and obtained better metabolic control than those who had other treatment regimens. She posed the question on whether the positive changes in the metabolic control were a result of treatment rather than education. She suggested that the duration of time over which the PDE program is attended is not important, but rather that the quality of the PDE may be the key.

Brown and Padgett et al. concurred on the limitations of the studies they reviewed. These included: inadequate description of study design, sample

characteristics and intervention content; neglect of cost-related outcomes; poor theory-base and poor assessment of behaviour change.

All three of the meta analyses in Table 1 complied with the criteria used for the evaluation of systematic reviews. However, the type of studies included in each of the meta analysis raises an issue. Although a validated rating system was used to analyze the methodological quality of the studies, single group pre/post design which are of a lower level of quality, were included rather than only including studies that used a control or comparison group design. The latter studies are of higher quality based on study design and their results tend to be more valid. Similarly, a recent systematic review of the literature on PDE found that the quality of meta analyses in this field is just too poor to produce reliable conclusions [73].

Primary quantitative studies

The literature search revealed 36 primary quantitative studies, which involved at least 1 year follow-up. Only seven of these studies met the criteria in the working definition and the inclusion/exclusion criteria for review and critical appraisal (see Appendix A). These studies included three randomized controlled trials (RCTs), one prospective controlled study and three prospective cohort studies with control or comparison groups. One study was conducted in Australia, one in the Netherlands, one in Germany, one in Argentina and three in the United States. Their main characteristics and findings are summarized in Appendix D.

The reviewed RCTs reported controversial results on the long-term effects of PDE programs in terms of improved metabolic control, reduced risks for cardiovascular disease and other patient outcomes (see Appendix D). The three reviewed RCTs included 1,477 adult patients with newly diagnosed type 2 diabetes and 206 with known type 1 and type 2 diabetes (with duration longer than 10 years) assigned to different PDE programs, using a variety of teaching strategies. Investigators defined newly diagnosed type 2 diabetes differently, used different sample selection and patient inclusion/exclusion criteria, different outcomes for diabetes management, different measures for some outcomes and had different follow-up periods.

The RCT conducted by Campbell et al in Australia [23] to determine the differences in effectiveness of four different types of PDE programs included 238 patients diagnosed with type 2 diabetes for less than 5 years. Patients were randomized to participate in "Minimal Education", "Individual Education", "Group Education" and "Behavioral Program". In the "Minimal Education", "Individual Education" and "Group Education" programs nurse educators and dieticians taught self-care in individual and/or group sessions using educational techniques (one program provided minimal education and two provided more intensive education). In the "Behavioral Program" a nurse educator taught self-

care in individual sessions using cognitive-behavioral techniques (see Table 2, Appendix D).

The investigators found no differences in the effects of four programs in terms of changes in knowledge, glycosylated hemoglobin levels (measured by HbA1c assays), body mass index (BMI), systolic blood pressure, and cholesterol levels at 1-year follow-up. Also, there were no significant differences in the effects of the programs in terms of proportion of patients visiting specialists or general practitioners, proportion of patients who changed treatment intensity, proportion of patients with hospital admissions, or patient satisfaction. The patients in the Behavioral Program had significantly greater reductions in diastolic blood pressure than those in the educational programs ($p=0.022$) and significantly lower attrition rate. It was not determined what factors led to lower attrition rate for the Behavioral Program (inclusion of behavioral strategies, fewer visits, and/or home-based visits).

In the multi-intervention RCT conducted in Germany [53], investigators placed particular emphasis on intensified health education (IHE) which integrated preventive measures such as change in lifestyle by health education and, if necessary, anti-hypertensive and lipid lowering drugs. The primary goal was to evaluate the efficacy of IHE on the course of type 2 diabetes and micro- and macro-angiopathy. This was a population-based study including only newly diagnosed patients (n=1139), controlled by diet after a 6-week screening phase with conventional dietary treatment. The patients were randomly assigned to an intervention group to receive structured IHE (including dietary advice and instruction about diabetes management, anti-smoking and anti-alcohol education, and advice on ways to enhance physical activity) and to a control group in which patients received no structured IHE. All patients were cared for by trained diabetologists. No information was available on who taught the structured IHE.

At the 5-year follow-up, glucose control (measured by adjusted fasting blood glucose levels) improved significantly in the intervention group as compared to the control group ($p<0.01$) but body weight remained stable in all study patients. Blood pressure levels, tobacco and alcohol consumption were significantly reduced in the intervention group patients when compared to the control group. Antidiabetic drugs were administered to significantly fewer patients in the intervention group as compared to the control group ($p<0.01$). Ratio of polyunsaturated to saturated fatty acids and physical activity increased significantly in the intervention group as compared to the control group ($p<0.001$; $p<0.001$ respectively). However, efforts to reduce over-nutrition and fat consumption were unsuccessful. Similar increase in cholesterol levels was found in both groups. No statistically significant difference in cardiovascular complication rate (incidence of myocardial infarction and ischemic heart disease) was detected between groups. The authors concluded that IHE is able to

substantially improve glucose control and reduce the necessity for drug treatment.

Glasgow et al. in the U.S. [46] conducted an RCT to evaluate the 12-month follow-up results and costs of a personalized medical office-based intervention focused on behavioral issues related to dietary self-management. The study included 206 patients attending an internal medicine outpatient clinic, with type 1 or type 2 diabetes, being 40 years of age and older, and primarily responsible for their own diabetes dietary self-management. The patients were randomly assigned to receive Usual Care Intervention ("high quality quarterly medical care" intervention with no focus on behavioral or psychosocial issues related to dietary behavior) or Brief Intervention (20-min personalized intervention and follow-up components focused on patient centered goal setting and problem solving).

At 12-months follow-up, the Brief Intervention produced significantly greater improvement than the Usual Care Intervention on multiple measures (Kristal Food Habits Questionnaire and 4-day food records) of change in dietary behavior ($p=0.023$) and on serum cholesterol levels ($p<0.002$). There were also significant differences on patients' satisfaction favoring Brief Intervention ($P<0.02$). However, no significant differences or improvement on either HbA1c levels or BMI values ($p=0.42$, $p=0.33$ respectively). The investigators found that the Brief Intervention was successful in and "cost-effective" for producing long-term improvement in dietary behavior and in serum cholesterol. Their "clinical impression" was that the combination of some components of the Brief Intervention package was responsible for the reported improvements. These components included efficient collection and use of data for personalization via touchscreen computer; mutually negotiated goals and collaborative problem solving that actively involved the patients; and follow-up phone contacts to provide support and prevent relapse. This combination reflected the increased attention and contact provided to the patients in the Brief Intervention group.

The other quantitative studies reviewed have also produced what appear to be mixed results – positive effects in some studies and no effects in others (see Table 2, Appendix D). Some studies that incorporated instruction on diabetes self-management skills and periodic contact and follow-up showed positive effects on glucose control variables and treatment intensity but less impact on weight loss variables. Other studies showed positive effects in terms of lifestyle changes reflected by significant reduction in some of the risk factors for cardiovascular disease. However, the prevalence of these factors remained high and improvement was not maintained in the long-term for all cases.

In relation to outcome measurement, most of the primary quantitative studies reviewed assessed physiological outcomes and gave less attention to the evaluation of the other outcomes of interest such as QOL, functional status, complication rates, diabetes-related mortality and health care services utilization.

Evaluation methods and in particular questionnaires were often developed by investigators but not validated.

The value of measuring PDE success in terms of outcomes that reflect the health status, well-being, or QOL of the patient with diabetes, rather than focusing only on knowledge and physiological outcomes, is being increasingly recognized [35, 64, 67, 69]. However, only few attempts have been made to evaluate the impact of PDE on QOL (see Table 2, Appendix D). Only one study [81] evaluated general and diabetes-related QOL. This study included patients with type 1 and type 2 diabetes who participated in a Comprehensive Diabetes Care Service (CDCS) including a 1-week diabetes education course consisting of daily group sessions. The control group were also patients with type 1 and type 2 diabetes, enrolled in a Group Model Health Maintenance Organization (GMH), who participated in a 1-month diabetes education course delivered in weekly group sessions. The two diabetes education courses had similar curriculum and followed the American Diabetes Association guidelines.

QOL indexes as measured by SF-36 showed no differences in non-diabetes-related parameters between the two groups [81] (see Table 2, Appendix D). CDCS patients had a lower score (felt worse) for their overall diabetes-related QOL (reflected by responses to two specific diabetes-related questions) at baseline than did GMH patients (who felt better at baseline). The overall diabetes-related QOL score improved in CDCS patients while the sense of well-being did not change in GMH patients over the course of the study. The study did not report on the QOL differences among the subgroups of patients with type 1 and those with type 2 diabetes.

Systematic reviews and critical appraisals

Seven reviews and critical appraisals of the published literature on the use of PDE provide further insight into its effects on diabetes management outcomes. The findings reported by these reviews are summarized in Appendix E. There were differences in the questions addressed by the reviews, in the methodology used, in the definitions used for PDE, and in the interpretation of the evidence that was reviewed.

Most reviews pointed to the methodological limitations of the published literature on PDE evaluations and identified gaps in the research on PDE that required further study [5, 26, 45, 47, 67, 73]. Several investigators noted the difficulty of separating PDE as a therapeutic tool from the medical therapy [26, 67]. Most investigators considered that PDE programs should be appropriately matched to the patients' needs and abilities [5, 26, 47, 67, 73, 105].

A review of PDE programs involving follow-up of 12 months or more [26] reinforced the potential value of including specific behavior-change strategies. One review of interventions for promotion of self-management in patients with

type 2 diabetes found that there is little reliable evidence to support the use of empowerment techniques [73].

Two reviews identified the need for more comprehensive, standardized, and objective measures of diabetes management outcomes [47, 67]. Their investigators suggested that information on participation and attrition rates, reasons for not attending or not returning to the program, problem-solving and decision-making skills, specific patient's characteristics of those who attend versus those who leave and not return, etc. can provide additional direction for the provision of PDE. Glasgow and Osteen [47] recommended that greater attention be focused on assessing the organizational practices of the location in which PDE takes place, specific patients' characteristics, QOL, as well as short-term and long-term outcomes (such as diabetes complications and mortality rate). One recent review suggested that studies need to measure morbidity and QOL outcomes and if possible mortality in addition to "surrogate" outcomes [73].

CRITICAL APPRAISAL OF THE PRIMARY RESEARCH STUDIES

Limitations and data presentation

The primary quantitative studies reviewed did not meet the desirable criteria for methodological quality and several methodological problems limit the interpretation of the reported results (see Appendix D). These problems include:

- inadequate description of study design (methods for randomization were not described in most studies; description on how patients were identified and selected, if present, was confined to a few lines in most studies);
- inadequate description of patients' characteristics (description of the population is based on some clinical and demographic data in most studies; severity and/or type of diabetes measures and/or accurate diagnostic criteria were neglected in most studies; other characteristics such as race, socio-economic status, educational levels, co-morbidity, and presence of complications were rarely described);
- inadequate description of the assessed PDE programs;
- inadequate reporting of the results in some studies (3/8 studies included both patients with type 1 and type 2 diabetes, used the PDE programs for all, and did not report the results separately);
- lack of blinding;
- reliance on self-reported data for measurement of self-care skills, changes in lifestyle and patients' satisfaction;
- only few studies reported the attrition/attendance rates and discussed their potential influence on diabetes management outcomes; and,
- for both participation and attrition there is little information concerning the comparability of those patients who participated (or completed the follow-up assessments) and those who did not.

The assessed PDE programs differed in many important dimensions: contact time, timing of sessions, delivery style (methods, strategies, tools, individual vs. group sessions), delivery setting (home, diabetes center/clinic, physician office), and provider (multi-professional team vs. individual provider, with different professional background, patient-provider interaction skills, and training as diabetes educators). Few studies described in some detail the PDE program(s) under study (see Appendix D):

- Most of the reviewed studies did not make explicit the educational objective of the assessed PDE programs (what people are expected to know or to be able to do at the end of the program).

- No study gave adequate information on how the instruction/teaching methods or learning activities were carried out.
- No study explained why certain methods were used for instruction/teaching to reach the educational objectives (whether belonging to the clinical, cognitive, psycho-motor or psycho-affective domains of the diabetes management).
- Few investigators described the learning methods and teaching tools used by programs.
- Most studies indicated who carried out the education in both groups, but only few provide information on the educator's training and none specify the psychopedagogical background.
- Some studies do not specify whether the program was given for small or large groups and others do not provide the number of participants attending the group sessions or the kind of group setting.
- Most studies specify the frequency and the duration of the educational intervention. Some just cite the frequency.
- Most studies report very little information on the content of the educational intervention.
- Most studies mention that the program was offered in an outpatient setting. However, no study gives detailed/accurate description of the setting and learning conditions under which the PDE takes place.
- Little information is provided on variables such as time to learn and cognitive or motivational approaches.
- Little information is given on the identification of patient's educational needs and on their psychosocial barriers. No link has been shown between patients' needs, educational objectives and the time devoted to the learning process.

Furthermore, no studies reported on how the patients perceived the education received and/or on how the patients evaluated the components of the program.

Discussion

The differences between the results obtained by the primary research studies reviewed may have been influenced by the different approaches taken by their investigators (see Appendix D). The results are not directly comparable because studies differed in the design, sample size, length of follow-up, and study population:

- Studies selected their patients using different sources, different inclusion/exclusion criteria, and different criteria for diagnosing type 2 diabetes.

- Different methods were employed for evaluation of the therapeutic impact of the assessed PDE program on diabetes management outcomes.
- The investigators used a variety of outcome measures (with different cut off limits and ranges for normal values) to evaluate and report on the same variables.
- Evaluations took place over different ranges of follow-up periods.

The clinical significance of the effects reported by the reviewed primary quantitative studies has yet to be established. The answers to the questions on "what kind of formal PDE program delivered in outpatient settings is most effective in the long term, for what category of patients and under what circumstances" remain uncertain. The main reasons include:

- None of the studies measured the efficacy of the assessed PDE program as a separate entity from diabetes treatment and the appropriate role of PDE in the diabetes management was not assessed. It was not clear whether the effects were the result of PDE, the result of administered medication, the result of both combined with the attention and care from providers and/or educators, or whether the results where influenced by any other components of the PDE approach and delivery.
- None of the studies determined whether detection of diabetes-related complications was improved and complications could be avoided in the long-term due to the therapeutic impact of the assessed PDE programs.
- No follow-up data were available on patients in whom the assessed PDE programs were shown to be ineffective to compare with follow-up data in patients in whom the same program was shown to be effective in terms of diabetes outcomes.
- None of the studies determined the differences between the long-term diabetes outcomes in those who attended the PDE program versus those who did not.
- None of the assessed PDE programs showed significant impact in terms of reduced rate of long-term diabetes-related complications.
- None of the studies determined a significant impact of the assessed PDE programs in terms of reduced rate of diabetes-related hospital admissions in the long-term.
- No significant differences have been determined between the effects of the assessed PDE programs in terms of changes in the proportions of patients visiting primary care providers and/or specialists and frequency of these visits.

CANADIAN STUDIES

None of the Canadian studies met the inclusion criteria for critical appraisal; however, it was felt there was a need to summarize the research that has taken place over the last ten years. This may help to identify gaps and to provide the background for future research activities.

Seven studies were retrieved. These varied in design and study objectives. The majority of the studies were program evaluations using a pre post design [97] or retrospective chart reviews [95]. The program evaluation studies were conducted either in the province of British Columbia [95] or Ontario [97]. The remaining two studies were unique:

- one study [94] conducted in British Columbia selected patients with poor glucose control and randomized them into two groups to determine if regular phone contact led to better glucose control; and
- the second study [103] using an 'extreme groups design' focused on determining psychosocial factors which could differentiate individuals into strongly adherent and strongly non adherent. The site of this study was the Nova Scotia Diabetes Centre.

The highlights of these studies are provided in Table 4 (Appendix F) and more detail can be found in Appendix G. The five program evaluation studies [10,37,68,95,97] differed considerably on various parameters such as the program design, frequency and length, individual versus group sessions, patients with differing severity of illness, outcomes measured and length of follow up. Of note was the substantial number of patients, 50% or more, lost to follow up. All five studies reported a benefit. Only two studies of the five studies used a subjective measure and mentioned the importance of including such a measure. The study by Vallis [103], which evaluated the role of diabetic-specific psychosocial factors in differentiating adherent individuals from non adherent individuals to their self care regime, emphasizes the need to include subjective measures. Their data suggest that cognitive, emotional and problem solving issues need to be addressed in order to improve adherence to self-care regime.

SECTION 2

ISSUES ASSOCIATED WITH DIABETES SELF-MANAGEMENT

Most of the PDE approaches assume that provision of information about the disease and associated complications and instruction in self-management skills, will lead to better diabetes control and patients will take steps to avoid or prevent potential complications [15, 34, 50, 64, 76, 87]. However, the asymptomatic though insidious nature of type 2 diabetes poses motivational issues that are distinct from a disease or illness with symptoms that cannot be ignored and which can interfere with the performance of their daily routines. Patients' motivation to learn, comply with their regimen and adhere to self-management behaviors over long-term is a very important factor in obtaining and maintaining good diabetes control and needs to be taken into account.

This section of the report outlines the main points that emerged from the literature which explored the bio-psycho-social context in which the patients adjust to the disease and learn how to self-manage it. It summarizes the information on the potential factors that may influence the impact of PDE on the patients' ability to self-management diabetes. The intent has been to extend understanding of what issues may be important to address when planning a formal PDE program or restructuring an existing one. Most of the information has been obtained from commentaries and discussions on the research on diabetes management and findings from questionnaire-based and qualitative research studies.

Patient compliance and regimen adherence

Major requirements in diabetes management are patient compliance with the regimen and adherence to self-management behaviors [14, 15, 33, 34, 53, 58, 62, 64, 67, 76, 96]. The concern with compliance has often been manifested in speculations about the patient's competence and motivation to metabolic control and general willingness to learn about diabetes, test glucose levels and follow therapeutic recommendations. Non-compliance has also been seen as the result of "ethnic beliefs" [7].

Rayman and Ellison [85] cite the findings from a qualitative research study on the meaning of compliance from the patient's perspective. The study found that health care providers and patients defined compliance differently and also had different treatment goals. The patients participating in the study developed self-management behaviors that suited their lifestyles, beliefs, personal life goals and priorities. The providers would have clearly defined some of these patients as non-compliant. According to Rayman and Ellison these findings indicated the need to place more emphasis on enhancing patients' efforts to live effectively consistent with their own goals and beliefs within the context of a chronic illness.

Many investigators suggested that patients may improve and maintain compliance and adherence to diabetes self-management if they are enabled to play more informed and active roles and have control over their own care [4, 14, 15, 17, 21, 30, 33, 34, 38, 39, 41, 42, 47, 50, 62-64, 67, 69, 73, 76, 80, 83, 87, 98]. Although medical therapy is important, long-term diabetes control outcomes also depend upon choices patients make about diet, physical exercise, and other health-related behaviors. These choices reflect patients' knowledge about their disease, their ability to monitor it, and their motivation to self-management behaviors. Many physiological, psychosocial and environmental factors may influence and determine the extent to which patients are able and willing to contribute to their own self-care.

Barriers to diabetes self-management behaviors

To understand the factors that may enable patient's motivation, the process of diabetes self-management must also be examined from the patients' perspectives. The qualitative research reviewed have documented the difficulties people with diabetes have living with their disease, complying with their therapeutic regimen and adhering to self-management behaviors [7, 30, 36, 49, 52, 69, 85, 89]. The identified issues of rigor (see Table 5 and Discussion in Appendix H) do not allow for a high level of confidence in the credibility, validity and transferability of these research findings. However, they add understanding of patient-perceived barriers to diabetes self-management and their effects on diabetes management outcomes. According to the participants in these studies managing diabetes effectively depends on the individual's decision to take control. As individuals learn about diabetes and the practical skills of managing diabetes they develop an ability to read body cues as well as expertise in how to make self-care decisions.

Findings from the qualitative research reviewed suggest that poor adherence and compliance may be rooted in the complexity of what has to be learned, managed and integrated with the patient's personal identity and current lifestyle. Decisions related to diabetes management and self-care must be congruent with patients' views of themselves within the context of their lives. The routine but complex decision-making process was grounded in faith, trust, support, values and beliefs. Family and personal events, personal views of themselves, health beliefs, attitudes toward diabetes, current health status, relationships with significant other/family members/friends, attitudes of and relationships with diabetes care and education providers, and anticipation of the future may all be incorporated in the decision making process. Patients wanted to maintain their previous lifestyle and considered the impact of the therapeutic regimen on their lives. To modify behaviors, they needed to perceive advantages of the changes as greater than the perceived disadvantages. The decision to assume control of diabetes management was perceived as a positive turning point in the patient's life, giving the individual a sense of well being.

Some reviews, commentaries and discussions on diabetes management, [8, 15, 17, 21, 33, 35, 38, 42, 47, 34, 50, 58, 62, 63, 64, 67, 73, 80, 83, 86] and questionnaire-based studies [12, 14, 41, 54, 56, 59, 76, 78, 84, 91, 97, 98, 103, 105] also indicated that many variables may impact compliance and adherence in diabetes self-management. The following summary outlines the variables that emerged most often in the above mentioned papers and summarizes the implications of their influences on diabetes self-management behaviors. These variables have been grouped into the following four broad categories: patient's characteristics, patient's social and environmental context, the disease itself, and the patient's interaction with diabetes care and education providers.

Patient's characteristics

Some investigators suggested that patient's characteristics and the amount of stress and style of stress management are predictive of self-management behaviors and influence the success of the regimen on diabetes control:

- Patient's profile is an important factor in diabetes self-management behavior resulting in a broad spectrum of attitudes and health behaviors depending on variables such as age, gender, health status (disease severity, co-morbidities, complications), ethnicity, culture, socio-economic status, marital status and education.
- Limited knowledge about diabetes and its complications and diabetes self-management skills can interfere with implementation of effective diabetes management regimen. However, knowledge is a necessary but insufficient condition for the behavioral change needed to ensure improved diabetes outcomes in the long-term.
- Learning abilities and literacy of each individual have been identified as important factors that influence diabetes self-management.
- Personality features such as extreme personality styles, low self-esteem, external locus of control, or poor ego development have been associated with poor compliance and adherence in diabetes self-management. Hardiness or a personal resistance to stress and self-efficacy have been correlated positively with compliance and adherence to self-management practices and may have a positive impact on diabetes management.
- Patients with diabetes may be more prone to eating disorders or depressive and anxiety disorders including blood and needle phobia, which may interfere with diabetes self-management practices. Other psychiatric disorders such as substance abuse and personality disorders may also be barriers to behavioral change.
- Health beliefs (including thoughts about health and illness, perception of health in the presence of illness, understanding of susceptibility to illness and perceived efficacy of therapies) and ethnic understanding and

conceptualization of diabetes may have a strong impact on adherence to diabetes self-management behaviors. Perceptions of health and well being appear to be important in coping with the stresses of disease but not necessarily with metabolic control. Patients may be more attentive to and concerned about controlling symptoms and maintaining a sense of well being than maintaining metabolic control.

- Strategies for coping with specific problems or stress may affect the patient's ability to self-manage diabetes. Denial is often used. Patients who overuse the defense mechanisms may be unable to express and deal with their feelings of vulnerability. They may act out their frustration by being non-compliant with the medical regimen or develop stress-induced illness.
- Effects of trauma such as psychological distress, psychiatric disorders and certain coping styles may be direct barriers to behavioral change.

The social-environmental context

The social-environmental context includes the web of organized, emotionally based, interpersonal ties within which patients organize the experiencing of diabetes and manage their disease[12, 15, 21, 28, 30, 33, 38, 41, 42, 47, 49, 50, 52, 58, 74, 85, 89, 92, 96, 99, 104, 106]. Patient's current living situation, social support, practices of the health care organizations, health insurance status, time, cost and location of the therapeutic regimen, community resources to support diabetes care and education, and safety of the environment potentially have a great influence on diabetes self-management behaviors. Findings include:

- Concerns about managing other stresses (such as unemployment, financial problems, illness or death in the family, or marital breakdown) and life commitments may compete with recommendations for diabetes self-management behaviors. Patients often attend to the family members' concerns before meeting their own diabetes self-management needs.
- Support from family and close social networks (including friendship networks) has also been identified as an important factor. How the family is structured, its beliefs, and problem-solving skills, and its patterns of emotional interactions have been shown both to enhance diabetes self-management or to exacerbate the stresses associated with it. Receiving support from friends in addition to family support has been associated with improved self-care behaviors. There has been far more attention given to social support in the family than in the work place [33].
- The extent to which third parties will reimburse diabetes care and education activities, may have a major influence on whether patients will participate in a given program.
- Organizational attributes, program logistics, and level of support resources in the surrounding community may also have major effects on whether patients

will participate in a diabetes care and education program. A program that includes family members, a large amount of group interaction, and shared exercise sessions may produce an improvement in social support measures.

- Safety of one's environment may also be an important factor for some individuals.

The disease itself

Barriers to behavioral change may come from the disease itself and/or as a result of the diagnosis, the regimen and/or the complications [12, 15, 17, 30, 33, 42, 52, 54, 56, 60, 63, 76, 80, 98, 99]:

- Irritability and depression can be induced metabolically as a result of fluctuations of glucose levels.
- The diagnosis of diabetes itself provokes a grieving process with rejection or anger responses that may affect the adherence to self-management behaviors and response to the therapeutic regimen. Reactions to diagnosis can range from apathy to catastrophizing, either of which may impede behavioral change. Stress reactions may represent a barrier to metabolic control by altering blood sugar levels. Emotional distress may cause the patient to over- or under-eat, make mistakes in medication administration, and to disregard activity needs. Self-management for distress may cancel diabetes self-management. Extreme anxiety levels about having diabetes may interfere with diabetes self-management.
- Many people with type 2 diabetes do not engage in all prescribed diabetes self-management behaviors or do so incorrectly. Certain aspects of the therapeutic regimen, such as dietary restrictions, meal schedules, and others (which involve unpleasant and socially unacceptable behaviors) often separate patients from the routines of their lives. Patients find it particularly difficult to deal with changes in diet. For many people, food represents a connection to emotional and social needs. Other people may encounter barriers to diabetes regimen because of their socio-economic context and/or lack of knowledge about what foods to buy for their dietary regimen. Exercise has also been identified as a difficult aspect of the diabetes regimen for patients to manage.
- The anticipation or onset of diabetes-related complications may also represent barriers to diabetes self-management. Fear of complications may prevent acceptance and problem solving. The time lapse between the diagnosis of diabetes and the onset of complications may make it difficult for patients to link present care with future consequences.
- The progressive nature of the disease, compounded by the clinically manifest complications, may add further psychological stress. Also, some particular complications (deficit of vision, cardiovascular functioning, dexterity and

ambulation) can make it difficult to exercise, test blood glucose levels accurately or administer medication (particularly insulin) appropriately.

Patient's interaction with diabetes care and education providers

Characteristics and elements of the patient's interaction with the diabetes care and education providers may interfere with implementation of effective treatment and with patient's motivation for self-management behaviors [8, 30, 33, 34, 36, 38, 52, 58, 63, 64, 67, 69, 73, 74, 83, 85, 89]. Problems related to patient's satisfaction, or coordination among different providers involved in diabetes care have been identified as having a major impact on the patient's acceptability of the regimen. Also, who provides diabetes care and education, the provider's beliefs and attitudes and the established patient-provider relationship are important factors.

These factors have been shown to structure the experiencing and management of the disease and influence the patient's motivation and consequently the effect of the regimen on the diabetes outcomes:

- How the provider defines and communicates the tasks facing the patient, whether he/she views the patient as a partner in care, and agrees with the patient about the type of relationship they have, have been positively associated with patient diabetes self-management behaviors.
- Interactions characterized by high degrees of patient involvement, patient control and information seeking, and expression of emotions by both patient and provider have also been correlated with improved diabetes outcomes. When patients were encouraged to participate in decision making and the flow of expertise occurred in both directions (patients relied on providers for expert information and provided expert self-information to their providers) adherence was improved. The effects of increased patients participation on improved outcomes have been related to issues of empowerment and control along with the greater likelihood of a treatment plan that is individualized to the particular needs of the patient's life.
- Poor patient-provider relationships discourage patients from offering input and asking questions. Harm may result when providers do not listen and do not value the experience of the person living with diabetes.
- The ability of the patient to access expertise on a 24-hour basis (which is ongoing communication with a team of health professionals for problem solving, feedback, and reality-based reinforcement guides) has been identified as pivotal for the success of diabetes management.

Physician knowledge, beliefs and attitudes about diabetes and its management have been identified as important factors that influence patient diabetes self-management and the success of the therapeutic regimen on diabetes management outcomes [7, 30, 33, 34, 38, 67, 83, 85]:

- Physician's reaction at the time of diagnosis may influence the patient's attitudes towards the disease and consequently compliance and adherence to the self-management behaviors and the impact of the therapeutic regimen on the diabetes management outcomes.
- Physician's skill in communication and interaction with the patient are important to both adherence and satisfaction with care. Patients are more likely to adhere to treatment recommendations when their physician provide clear explanations and positive comments. The amount of time spent with the patient and the number of tests ordered may also influence adherence although the reasons for these findings are unclear [30, 85].
- Physician's deficiencies in knowledge of diabetes management and physician's failure to refer the patient for PDE may also be limiting factors.

The potential impact of each of these groups of variables on behavioral change and diabetes outcomes has been studied in relative isolation of the others. This fact may have delayed the development of diabetes care and education approaches tailored to overcome the identified barriers and respond to individual patient's needs.

PDE and behavioral change

Some evidence suggests that the success of PDE interventions on behavioral change may be enhanced if the patients are involved in the planning of the educational approach and content [32, 43].

Peyrot and Rubin [82] suggested that any good PDE program must teach self-care skills and motivate patients to use these skills. They recommended that educators should focus on helping patients to identify the areas of self-care most amenable to change or most in need of change.

Colagiuri et al. [27] found that "knowledge is neither dependent on, nor a good discriminator of, patient-selected priorities". They suggested that education directed solely at patient's educational priorities "may leave knowledge deficits which could compromise diabetes care".

Bonnet et al. [14] pointed out that the difficulties in educating patients may be due to their diverse characteristics, backgrounds, varying degrees of motivation and differing learning abilities. The investigators recommended that the time scheduled for PDE must be based on the difficulty of the skills to be taught and not be set a priori.

Patient-educator interaction and behavioral change

It has been suggested that characteristics of the patient-educator interactions may interfere with the process of the patient's motivation and personal integration necessary for long-term behavioral change [4, 7, 15, 30, 33, 38, 42, 50, 52, 64, 75, 80, 85, 86]. Interference may result:

- When educators ignore the realities associated with the disease and its management and those associated with the patient's characteristics and social-environmental context.
- When development of the educational approach and self-management plan does not involve a team of professionals, patients and their families.
- When patients perceive educators as being critical of them.
- When educators place more focus on what is to be presented rather than on the resources and ideas of the patient.
- When teaching methods, tools and materials do not meet the patient's needs.
- When the instruction is too theoretical and of little practical use.
- When educators fail to refer the patient to other professionals skilled in facilitating diabetes self-management behaviors (such as mental health professionals).
- When only dietitians and nurses staff the PDE centre. The absence of physicians (perceived as authority figures) may send the message that PDE is less important than medical treatment. The absence of mental health professionals (psychologists) may be a problem as they can stimulate important discussions about barriers to diabetes self-management. The absence of professionals with expertise in physical exercise may also be a barrier to behavioral change since they can provide education about exercise to avoid injuries and acute diabetes-related complications.
- When only female health care professionals staff the PDE centre. The absence of male staff may communicate to male patients that diabetes self-management is a "female thing" and behavioral changes are less likely to result.
- When educators lack appropriate and current knowledge and skills including effective communication strategies.
- When educator's approach and delivery of PDE are not culturally sensitive.

IMPLICATIONS FOR THE PDE PROCESS

The needs for education and social support of adults with type 2 diabetes require providers to develop new kinds of partnerships to improve self-management. The partnership needs to be implemented across the disease cycle in accordance with the demands of each phase and the unique needs of patients, their family and/or careers. Based on all of the literature reviewed, the elements for an effective PDE process, considered to be appropriate for these patients, regardless of age, gender and race, have been structured as follows. These considerations summarize the implications of the various bio-psycho-social factors for planning or restructuring a PDE process, as cited by the reviewed literature. The PDE process should:

- Be an ongoing patient-centered process, based on thorough assessments of the individual patient's needs and abilities. The following should take place prior to starting PDE:
  - A review of the patient's experiences and understanding about diabetes, their expectations of the educational program, what they need from the provider, areas of concern or questions that they would like to address in the educational process and their level of interest in changing particular aspects of their behavior.
  - An understanding of the patient's diabetes-specific needs and health beliefs and fears, view of self-care, self-care and problem solving skills, social environment and level of diabetes-related emotional and practical support.
  - An understanding of the patients' potential barriers to self-care, coping skills, commitment to behavior change, barriers to behavior change, and existing knowledge base and needs.
  - Adjust the PDE approach to address any identified factors (such as patient's fears, deficits or difficulties in diabetes self-management) that may be creating problems and support patient's healthy attempts to cope with high levels of anxiety.
- Focus on both educational and behavioral strategies:
  - Sessions should go beyond knowledge and skills by specifying the diabetes self-management behaviors patients need in order to implement the regimen and make the necessary changes in lifestyle.
  - The nature of diabetes self-management should be discussed and explained at the beginning of the program to help patients understand both why the information presented is important and that the role of the diabetes care and education providers is as a source of expertise, support, and inspiration.

  - During the sessions educators should minimize teaching the diabetes facts and maximize instruction on how to perform self-management skills and problem-solving, how to overcome barriers and make the necessary lifestyle changes and then to maintain them in the long-term.
  - Strategies should target those barriers that can be changed most readily and those changes identified as most important.
  - Strategies should address both physical and psychosocial barriers.
- Be sensitive to the elements of patient's social-environmental context that support or hinder compliance and adherence to self-management behaviors by:
  - Allowing the presence of the patient's spouse, partner or other significant family member, whenever possible, to identify potential sources of burnout and help the patient and family develop new ways to manage diabetes suitable for all those involved.
  - Exploiting the natural support resources that family and friends can provide for patients.
  - Assisting patients in identifying and accessing support systems.
- Complement the services provided by other diabetes care members including services from primary care providers and mental health professionals (it must be coupled with expert adjustment of medication and expert training in dealing with diabetes-related behavioral and psychological issues).
- Allow the patient to frequently access expertise for problem solving, feedback, and reality-based reinforcement guides.
- Allow a close collaboration between the patient, any caretaker and the diabetes team (including at least the diabetes educator and the physician) built on trusting and supportive relationships, which is necessary to negotiate goals that are specific and achievable:
  - Clear-cut educational objectives should be agreed on between all members of the care team and the patient, based on negotiated goals that are specific and achievable.
  - Priorities and outcomes of the teaching intervention must be established with the participation of the patient and any caretaker.
  - Educational objectives should be subdivided based on priorities ranging from more urgent to less urgent ones, making PDE a continuous process with different timings, aiming for long-term outcomes including prevention/delay of complications and good management when they occur.
- Be coupled with positive reinforcement of learned skills and healthy behaviors and opportunities for repetition.

- Include periodic follow-up components with re-assessment of barriers, necessary to ensure continuity.
- Use both individual and group sessions, when possible. Individual sessions are probably the best for initial contact, when educational objectives need to be defined to respond to individual's needs, particularly in the presence of severe emotional distress.
- Include mediated presentations (such as videotapes and/or computer-aided instruction) which should complement, not replace, human interactions.

The elements listed above were not chosen on the basis of the methodological quality of the literature reviewed. Given the fact that PDE aims at changing behavior to better self-manage the disease, it was decided to also include factors uncovered by various types of research, other than quantitative studies.

Many of these elements have been previously identified and reported by Pichert [93] and Tan [93] as effective ways to improve PDE and enhance patients' compliance to prescribed regimen for diabetes control.

SECTION 3

Discussion

Research in PDE in the last decade, has redefined objectives for PDE at the individual patient level to include motivations, attitudes and behaviors as well as the traditional factual and practical knowledge. The reviewed literature reflects an agreement among diabetes care and education providers that good self-management is a result of a knowledge base, changes in lifestyle and certain behaviors and effective problem-solving and decision-making skills. The emphasis on patient-centered perspectives, self-efficacy, and empowerment in PDE legitimized the patient's experience and control of the choices that make up the everyday diabetes management experience.

Quantitative research studies

This assessment revealed that there is still a lack of consensus on the value and impact of formal PDE on long-term diabetes control necessary to prevent/delay diabetes-associated morbidity and mortality and improve patients' QOL. According to the reviewed literature the real problem for research in PDE is not to demonstrate the effectiveness of PDE, which is already seen as a necessary component of the diabetes care and management regimen. The real problem is to determine which approach and components are more effective in obtaining and maintaining good diabetes control in the long-term and for what group of patients. However, the evidence produced by the reviewed quantitative research, has not been able to provide conclusive answers to these important issues associated with the use of formal PDE.

The issue of how comprehensive the formal PDE programs should be to produce long-term beneficial effects has yet to be clarified. The assessed programs in the reviewed quantitative research studies were generally comprehensive, involving many components (instruction in diet, exercise, medication, glucose testing, problem-solving and changes in the prescribed medication). Some of these programs produced overall improvements in terms of various diabetes outcomes.

However, the inadequate description of the assessed programs limited the interpretation of the reported results. It was not clear how much each component of those programs contributed to the reported improvements or which changes in self-care behaviors were responsible for the improvements. None of the studies attempted to determine how particular components of the PDE delivery and patient characteristics predict long-term diabetes management outcomes. Few studies discussed the potential influence of some of the PDE program components on the reported results. Although the reviewed meta analyses have suggested that different types of PDE programs have different levels of impact, the effects of individual components in comprehensive programs have not been established.

Another important problem concerns the category of patients with type 2 diabetes who would benefit the most from such programs. The evidence produced by the reviewed quantitative research studies did not permit a conclusive answer to this question either. Some studies included patients with type 1 or type 2 diabetes and did not report their results separately although, theoretically, the two types of diabetes call for distinct objectives and educational interventions. Some included only patients with type 2 diabetes (newly diagnosed and/or known type 2 diabetes) but used different diagnostic criteria. Most studies provided inadequate description of patient's characteristics and only a few reported attrition rates and discussed their influence on the results.

The literature reviewed identified the difficulty, or maybe the impossibility to measure the efficacy of PDE as a separate entity from diabetes treatment, because diabetes management incorporates both self-management education and treatment. It is not clear whether the level of prevention, detection and/or management of diabetes-related complications improves and are maintained in the long-term. It is still not clear whether the level of diabetes control is the same, better, or worse in the patients who attended or received formal PDE as compared to those who did not. Also, little is known about the reasons why some people do not attend formal PDE programs, and what factors would motivate them to attend. The relationship between attendance, the components of the program, the number of follow-up visits, the type of follow-up and the accessibility of the PDE staff and expert advise has yet to be clarified.

Another issue of interest concerns the amount of time required to educate patients with type 2 diabetes (for both initial and continuing education). In the reviewed quantitative research there was limited description of the learning conditions under which PDE takes place and very little information is provided on variables such as time to teach/learn. Campbell et al. [23] suggest that "programs that are more intensive in terms of patient time and resources may not produce greater improvement than less intensive programs". However, there is no consensus on this issue. Brown [20] states that future research should explore the types of PDE interventions used rather than the length of service provided.

In relation to outcome measurement, there is still a lack of consensus on which are the most relevant measures of PDE success or failure. Most of the primary quantitative studies reviewed assessed physiological outcomes and gave less attention to other outcomes of interest such as diabetes-related morbidity, mortality and health services utilization. Although QOL has been identified as an important component for comprehensive evaluation of alternative approaches in PDE (since "compromised QOL poses a risk for non-compliance with increasingly intensive and intrusive" diabetes regimens [20]), it has been neglected as a priority in PDE research.

The reviewed literature suggests that non-diabetes-related factors such as socio-environmental context may be more important with regards to QOL than diabetes-related factors. It has also been suggested that differences in QOL as a function of demographic variables (age, gender, marital status, education level, insurance coverage, social support), medical history (type of diabetes, complications, co-morbid illnesses) and self-management factors (type of treatment, physical activity) need to be considered [4, 35, 48, 57, 86, 102]. Further research is needed to define diabetes-related QOL and ways to elicit the views, concerns and values that are important to patients and to determine the impact of diabetes on a person's lifestyle.

Qualitative research studies

Research has measured changes in diabetes knowledge and skills and in metabolic control obtained through formal PDE but little research has been conducted to determine how do patients make their diabetes-related decisions and how much information and decision-making are they comfortable with. The qualitative research reviewed and questionnaire-based studies offered insight into the social, emotional and experiential phenomena of living with type 2 diabetes as perceived by patients. These studies explored the meaning of diabetes to patients and to their families and friends, the attitudes and behaviors of patients and health care providers toward the disease and its management, and/or the bio-psycho-social context in which the patients adjust to the disease and learn how to self-manage it.

The findings from the qualitative research studies described important variables, particularly in terms of the social dynamics and the subjective realities of patients living with diabetes, factors that potentially influence the impact of diabetes care and education regimens on patient outcomes in the long-term. They were useful in illuminating the findings from quantitative research studies, by helping to understand better the context in which PDE should be applied to be successful in promoting self-management behaviors in adult patients with type 2 diabetes.

Instead of focusing on disease and pathophysiological processes the diabetes education providers may need to turn their attention to understanding the perceptions of the disease and its management from the viewpoints of patients with type 2 diabetes making the decisions. Such a re-orientation incorporates how individuals and their families respond to, make sense of, cope with, and adapt to symptoms and disabilities. Patient's interactions with the diabetes care and education providers must allow exploration of the effects of the values, beliefs, and expectations on decision-making, especially the impact of the therapeutic regimen on patient's life. However strategies for addressing patient's bio-psycho-social barriers remain underdeveloped.

CONCLUSIONS

The reviewed literature showed that:

- the diabetes literature its consistent in its endorsement of the importance of using a PDE approach as a component of diabetes care necessary to promote self-management;
- knowledge about diabetes and self-management skills are necessary but not sufficient to ensure good diabetes control in the long-term in order to prevent/delay complications, reduce mortality and improve patients' QOL;
- recently published research suggests that challenging goals for diabetes self-management cannot be achieved until barriers associated with patient's characteristics, patient's social and environmental context, the disease itself, and the patient's interaction with diabetes care and education providers are resolved.

The available evidence reported by the **quantitative research** did not permit to draw reliable conclusions on whether formal PDE is effective in promoting self-management in adults with type 2 diabetes in the long-term to prevent/delay associated morbidity and mortality and improve patients' QOL. The reviewed primary quantitative studies did not meet the desirable criteria for methodological quality and several methodological problems limited the interpretation of the reported results. Their reported results were not directly comparable since the investigators used different approaches and data presentation was inadequate.

The reviewed RCTs reported mixed results on the long-term impact of formal PDE in terms of improved metabolic control and reduced risks for cardiovascular disease. However, the clinical significance of the reported results has yet to be established.

The findings outlined by this assessment yielded similar results to previous ones:

- there is no consistent pattern of effect across outcomes based on type of intervention, length of educational intervention, core team composition or type of educational setting; and
- there is no standard method to describe formal PDE programs, thus making it difficult to replicate studies.

The available evidence reported by the **quantitative research** reviewed did not permit conclusive answers on:

- which types of programs or what components are most effective in improving the ability of adults with type 2 diabetes to self-manage their disease in the long-term; or
- which groups of patients might benefit most.

Findings from the **qualitative research** reviewed identified factors that potentially influence the impact of diabetes care and education regimens on diabetes control outcomes in the long-term. They were useful by helping to understand better the context in which PDE should be applied to be successful in promoting self-management behaviors that in turn may lead to good diabetes control in the long-term.

The past decade has witnessed a shift from traditional approaches of PDE to a focus on patient-centered perspectives, self-efficacy and empowerment issues. To address this shift, there is a need to determine program reach and appeal to different patient categories, and its impact on patients' QOL. Administrators of PDE programs should be aware that the trends in the delivery of PDE suggest a need for an ongoing patient-centered PDE approach, described as a step-by-step process which involves the diabetes care and education providers, the patients and their caregivers. These trends call for:

- the assessment of the patient's bio-psycho-social barriers, goal setting according to the assessment, educational interventions, follow-up and reassessment;
- focus on meeting the patient's needs and overcoming patient's barriers to self-management behaviors, and continuous reinforcement of patient's positive behaviors;
- the development of trustful patient-educator relationship and the existence of good partnership with the other members of the diabetes management team;
- measurement of success in terms of long-term outcomes such as reduced diabetes- associated morbidity and mortality, and increased QOL;
- measurement of benefits in terms of short-term outcomes (such as improved metabolic control; weight loss; maintained positive behavioral changes; and decreased number of barriers to self-management) that act as stepping-stones to the desired long-term outcomes; and
- data collected for each outcome by using a more standardized set of validated instruments.

None of the Canadian studies published over the last decade met the criteria in the working definitions and inclusion criteria for review. All Canadian studies discussed in this report focused mainly on program evaluation, not on determining the effectiveness of formal PDE. Canadian investigators can build upon the experience described in this report. Future research should attempt to overcome the methodological limitations of the studies reviewed.

APPENDIX A: METHODOLOGY

A) Literature search

A literature search of relevant databases was conducted for papers published between 1966 and May 2000, limited to English or French, and humans. The databases searched included MEDLINE, CINHAL, HealthSTAR, EMBASE, ERIC database, PsycINFO, The Cochrane Library, ISTAHC database and Dissertation Abstracts database.

The following keywords were used alone or in combination to ensure a high recall rate of the relevant references: 'diabetes mellitus', 'diabetes', 'diabetes mellitus, non-insulin-dependent', AND one OR more of 'effectiveness', 'impact', 'evaluation', 'outcome assessment (health care)', 'outcome and process assessment (health care)', program evaluation', AND one OR more of 'health education', 'patient education', 'education', and 'self-care'.

This literature search resulted in approximately 2,400 citations. After a preliminary scanning of all citations, only articles published between 1990 and August 1999 were selected as many changes in diabetes education and care occurred in the late '80s and early '90s.

The main focus of the assessment was to determine what were in the published literature about the efficacy/effectiveness of the use of the existing PDE programs in the management of type 2 diabetes in adults in terms of long-term patient outcomes.

B) Working definition

For the purpose of this review it was decided to focus on articles that reported on programs matching the following working definition:

- outpatient-orientated;
- formalized (with participation in a class/course/session, instructed by at least one dedicated health professional educator, and with a defined curriculum);
- designed only for adults (aged 18 and over) with type 2 diabetes (although may include both type 1 adults and type 2 adults);
- offered to heterogeneous patients in terms of age, sex, and race; and
- with at least one-year follow-up component (within which patients have more than one contact with the program).

For the purpose of this assessment, it was decided that in order to define the real success, the reported results need to reflect the impact of PDE for at least 1 year on clinical (metabolic control), cognitive, psychomotor (self-care behavior, skill performance) and affective (psycho-social concerns) domains of the diabetes self-

management. Consequently it has been decided to include only those primary studies that reported on the impact of PDE for at least 1 year on:

1. one or more of the following objective outcomes:
   - physiological/physical outcomes (such as changes in glucose levels; changes in body weight; morbidity; development/prevention of acute/chronic complications; reduction in medication; functional status; mortality rates);
   - utilization of health care services (readmission in hospital; use of ER; physician visits; etc); AND
2. one or more of the following subjective outcomes (using a specific, validated instruments/scales):
   - patient knowledge;
   - self-care behavior (compliance with regimen/diet/medication, skills, self-efficacy);
   - psychosocial outcomes:
     - social support;
     - adherence to self-care (anxiety, coping, perceived stress, denial of disease, attitudes and beliefs involving diabetes and education);
   - overall or diabetes-related quality of life;
   - patient satisfaction.

C) Selection of the material

From the references identified, a selection was made and full text articles that met the following inclusion criteria were retrieved:

- primary quantitative studies (controlled or comparative studies) and meta analyses, which evaluated efficacy/effectiveness of any PDE that matched the working definition, used alone or in combination with treatment, with intent to improve the patient's ability to manage their diabetes as measured by both objective and subjective patient outcomes;
- primary quantitative and qualitative studies and meta analyses which included only adults (aged 18 years and over) with type 2 diabetes or both type 1 adults and type 2 adults;
- primary quantitative studies which compared inpatient- vs. outpatient-orientated PDE or formalized vs. non-formalized PDE;
- systematic reviews on the use of outpatient formalized PDE as a therapeutic intervention in type 2 diabetes patients; and

- questionnaire-based studies which included only adults (aged 18 years and over) with type 2 diabetes (or both type 1 adults and type 2 adults) and reported on issues associated with the use of PDE as a therapeutic intervention in these patients.

Based on the working definition and inclusion criteria, it was decided not to include:

- studies which evaluated efficacy of PDE designed and used exclusively for type 1 diabetes, gestational diabetes, secondary diabetes, impaired glucose tolerance (to prevent type 2 diabetes);
- studies which included type 1 and type 2 diabetes patients under 18 years of age; studies which included only children and adolescents (0-18 years);
- studies which evaluated efficacy/effectiveness of inpatient-oriented PDE;
- studies which had a follow-up period less than one year;
- primary quantitative studies which had a sample size of less than 15 patients in each arm;
- studies which evaluated the use of professional educational interventions and explored the providers'/educators' perspective on the success of the assessed PDE;
- studies which evaluated mutifaceted educational interventions (including both patient and provider education);
- studies on the use of PDE designed and offered to homogeneous ethnic groups (e.g., Hispanics, Native Indians, Blacks, etc); or
- letters, case reports and case series.

Further relevant articles were found by examination of the references listed in the retrieved papers. Papers published before 1990 were reviewed/quoted when appropriate.

Given the likely heterogeneity of educational interventions, settings, patient populations, and evaluation methods, it was decided to summarize the results of the reviewed studies in tabular form (see Appendices C, D, E, F and H).

APPENDIX B: METHODOLOGICAL QUALITY OF CRITICALLY APPRAISED STUDIES

In assessing the usefulness of the studies addressing the use of PDE and its long-term impact on the management of type 2 diabetes in adults, there seems to be a need to consider both the scope/purpose of the studies and the methodological quality of the evaluation/exploration undertaken. Design or type of the study, sample selection and description of study population, collection and inclusion of all relevant information are important considerations.

A) Criteria for critical appraisal of quantitative research studies

The methodological quality of the primary quantitative studies and meta analyses located in the literature search was considered in terms of the criteria formulated in this Appendix. These criteria were developed having regard to the information needed to confidently determine which PDE is most effective in promoting diabetes self-management in type 2 DM in terms of patient outcomes. Statistical methods used by investigators for data analysis were not assessed.

For **meta analyses** conducted to determine the effects of diabetes education on patient outcomes, the following aspects were considered:

- Important clinical question: precisely identified question.
- Detailed information of search strategy: search of appropriate databases, inclusion/exclusion criteria, and exploration of other potential sources explored.
- Assessment of methodology quality: each study was assessed according to some criteria and weighted appropriately.
- Appropriateness for combining studies: test for homogeneity.
- Robustness of conclusions: sensitivity analysis to determine the robustness of results.
- Generalizability: external validity or relevance of the studies included.

These criteria were formulated based on the material published by Greenhalgh [51].

For **primary quantitative studies** conducted to evaluate efficacy/effectiveness of any PDE as a management intervention in diabetes patients consideration of the following points was required:

- Study design: prospective/retrospective, controlled/not controlled, randomized/not randomized, cohort studies, pre-/post-intervention design, follow-up period, blinding.

- Selection and description of study population: sample selection and specification; patients' characteristics; inclusion/exclusion criteria; drop-outs; confounders.
- Characteristics of the PDE under study: objectives, methods, tools, curriculum, setting, core team; number and duration of classes/courses/sessions; frequency of and methods used for follow-ups.
- Findings: outcomes, outcome measures, reporting of results.
- Clinical validity: utility of the assessed PDE (information on the appropriate role of the educational program; determine attrition rate).

These criteria were developed based on the reviewers' experience and on the material published on critical appraisal of the medical literature in peer reviewed journals like British Medical Journal and Journal of the American Medical Association.

B) Criteria for critical appraisal of qualitative research studies

The methodological quality of the qualitative research studies included in the review was considered in terms of the criteria developed having regard to the issues of rigor needed to confidently determine the credibility and transferability of the findings of these studies.

For primary qualitative studies conducted to explore the context in the patients with diabetes adjust to their disease and learn how to self-manage it, the following issues of rigor were addressed:

- Clarity of the research question.
- Appropriateness of the qualitative approach to the question.
- Sampling method used to select setting and patients (mentioned and described in sufficient detail; included a full range of possible cases or settings; exhaustive exploration).
- Data collection and analysis methods (methods used were systematic and described in sufficient detail; audit trails described in sufficient detail; negative or deviant cases were searched for).
- Credibility and validity of findings (triangulation of sources present; concepts and categories clearly defined; quotes reproduced; findings independently and objectively verifiable; audio or video recordings; findings reviewed and independently interpreted by two or more investigators; findings returned to participants; presented alternative plausible explanations for findings; observer bias identified/discussed; study limitations discussed).
- Transferability of the results to other settings (theoretical sampling; saturation of data; context or setting sufficiently described; sample representative).

These criteria were formulated based on the materials published by Mayes & Pope [66], Morse & Field [70], and Murphy et al [72], with assistance from Sue Ludwig who has a PhD in Educational Psychology as well as a Master degree in Counselling Psychology. However, it has been suggested that many of the issues of rigor described above are highly controversial and would be considered inappropriate to be used as predefined criteria to assess methodological quality of qualitative research studies (Heather Maclean, personal communication).

This report does not include any critical appraisal of the **systematic reviews** or of the **other study designs** (such as the questionnaire-based studies) included in this assessment.

Since none of the Canadian studies included in the report meet the criteria in the working definitions and the inclusion criteria for review, they were not critically appraised based on methodological quality. These studies were selected if they:

- were conducted over the last 10 years anywhere in Canada;
- were focusing on the use of formal PDE designed to promote self-management only in adults (>18 years) with type 2 or in both type 1 and type 2 adults; and
- included heterogeneous populations in terms of age, sex, race.

APPENDIX C: META ANALYSES

CI - confidence intervals

ES - effect size

gp - group(s)

hr - hour(s)

min - minute(s)

mo - month(s)

pts - points

Table1: Meta analyses of educational interventions studies

Study	Study's characteristics	Author(s)' findings
Padgett et al. 1988 [79]	***purpose**: to evaluate the overall efficacy of educational and psychosocial interventions and to provide quantitative estimates of the relative efficacy of specific interventions in improving knowledge, psychological status, compliance and metabolic control ***inclusion criteria:** studies of the effects of educational and psychosocial interventions in diabetes mellitus during 1976 to 1986; control group or single group pre/post test design; minimum sample size of 5 in each group ***search:** MEDLARS, Excerpta Medica, Dissertation abstracts, NTIS, SSCI, ERIC, Psychological Abstracts, Sociological Abstracts, GPO. Key words included diabetes, compliance, patient education, behaviour, intervention, psychology, psychotherapy and counseling. Included published and unpublished studies. ***methodological quality:** used rating system based upon the work of Sackett and Haynes ***interventions:** patient education (didactic, enhanced),behavioral (dietary, exercise, blood glucose self monitoring), psychosocial (social learning strategies, relaxation training, counseling) ***outcome measures:** knowledge, physical, psychological, compliance ***test for homogeneity:** not mentioned. All studies were given equal weight, each contributing one overall mean ES and four categorical ES's. An unbiased ES for small samples studies was calculated following Hedges' and Olkin's methodology.	*Type of intervention and strategy – enhanced education (multiple instruction techniques including different combinations of diet, exercise, or self-monitoring instruction) was most frequently tested intervention *Context of intervention – most studies (63/94) were conducted in an outpatient clinic setting usually associated with a teaching and research hospital; 13/94 provided as inpatient intervention *Sample characteristics – 45/94 studies were conducted on insulin dependent patients; 25/94 targeted non insulin dependent; 19/94 included both. Sample size ranged from 5 to 859 subjects with an average of 79 per study. Overall average age 38 years with slightly more females (55% overall average). 20/94 studies were conducted exclusively on children and adolescents. *Study design – 53/94 control design (39 random assignment and 14 matching historical control) 41/94 single group pre/post test design. Average quality score 7.5 points with a range of 2 to 14 points (maximum 16 points). *Type of outcome – 71/94 used physical measures such as glycosylated hemoglobin and blood glucose levels. 23/94 focused on improvements on knowledge, compliance or psychological status. *Impact of study and sample characteristics – type of setting significantly associated with magnitude of effect size (ES), interventions conducted in inpatient settings yielded highest mean ES (.93 ±.59); overall rating of quality of methodology for each study was inversely related to ES. Weaker studies were significantly associated with higher ES values. Type of study design and assignment to treatment were inversely related to mean ES. Weaker studies were associated with inflated ES values. No significant differences were found between age, sex, types of diabetes, intervention types and mean ES. *Long term effects on selected outcomes - 14/94 calculated effects beyond the first post test period for 5 outcomes (blood glucose, glycosylated hemoglobin, body weight, knowledge and psychological status). Observed trends: independent of outcome measure, the effectiveness of the intervention decreases with time; ES for blood glucose, weight loss, glycosylated hemoglobin and knowledge test decreased from 6 to 12 mo follow up. Weight loss showed a negative ES. *Overall conclusion from the analysis of 94 studies revealed an overall mean effect size of 0.51, moderate significant improvement across all outcomes with physical and knowledge gain most effected followed by psychological status and compliance.

Table1: Meta analyses of educational interventions studies (cont'd)

Study	Study's characteristics	Author(s)' findings
Brown 1990 [19]	*__purpose:__ to determine the effects of patient education on specific outcome variables and the relationships between effects of education and characteristics of the studies and/or subjects. *__inclusion criteria:__ primarily adults with diabetes; an education intervention to improve patient knowledge, self-care behaviour; metabolic control and/or psychological outcomes; experimental design (treatment and control groups, one group pretest/posttest design); same setting for both treatment and control groups; measure of outcome in terms of patient knowledge, self-care behaviours (skill performance or compliance/adherence), metabolic control and/or psychological outcomes (stress reduction, coping, adaptation) *__search:__ MEDLINE (1966-1989), combined Health Information Data base (1978-1989), Psychological Abstracts (1967-1989), ERIC (1966-1989), Dissertation Abstracts (1961-1989) using the heading diabetes related to health education and patient education. Unpublished studies were identified through a survey of accredited master's degree nursing programs and contacts at the Diabetes Division of the Centres for Disease Control. *__methodological quality:__ scoring of: study design, type of subject selection, specificity of describing the study sample, type of diabetes and educational intervention, directness/objectivity of the outcome measure. Calculated weighted means. *__intervention:__ Education intervention was defined as any intervention given to a diabetic adult with the intent of improving the person's ability to manage the diabetes, whether it be in the cognitive, psychomotor, or affective domains. *__outcome measures:__ knowledge (dietary principles, composite); self-care (skill performance – insulin injection, urine testing; compliance/adherence – weight, dietary compliance); metabolic control (glycosylated hemoglobin, blood sugar, urine sugar, insulin dose, cholesterol, blood pressure, medical care – number & length of hospitalization); psychological *__test for homogeneity:__ homogeneity analysis of specific outcome variables, outliers were identified and removed	*Description of studies – 56/82 studies use control or comparison groups; 26/82 used one group pretest/posttest design. 84% of the studies were published since 1981. 32% were from unpublished sources. 39% of the studies combined Type 1 and Type 2 and 21% of the studies did not provide the information. *Quality of research – mean quality points 11.53 ± 3.29, range 5 – 18 (total possible 21 points) *Knowledge – weighted mean ES for knowledge of dietary principles 0.49 (95% CI 0.37-0.61) and 1.05 (95% CI 0.94-1.16) for composite knowledge *Self-care behaviours – weighted mean ES for insulin injection 0.23 (95% CI 0.05-0.40); urine testing 0.44 (95%CI 0.32-0.57); weight 0.17 (95%CI 0.08-0.27); dietary compliance 0.57 (95% CI 0.44-0.77) *Metabolic control – weighted mean ES for glycosylated hemoglobin 0.41 (95% CI 0.31-0.52); blood sugar 0.34 (95%CI 0.25-0.43); urine sugar 0.39 (95%CI 0.15-0.63); insulin dose 0.16 (95%CI 0.03-0.28); cholesterol 0.24 (95%CI 0.09-0.38); blood pressure 0.34 (95%CI 0.14-0.55); medical care 0.35 (95%CI 0.21-0.50) *Psychological outcomes – only14 studies measured this outcome, weighted mean effect size 0.27 (95%CI 0.12-0.42) *Correlation analyses of the relationship among study characteristics (publication date, attrition rate, mean age of patients, rating of research quality, length of the program and length of time between intervention and measurement of outcome) showed a statistically significant relationship related to age of the participants. Mean age was negatively related to knowledge of dietary principles, knowledge composite and cholesterol indicating the older the mean age of the subjects, the lower the effects of patient education. *Overall conclusion – patient education in diabetes care is effective in producing positive patient outcomes. Results are consistent with previously reported meta analysis conducted by the author (18).

Table1: Meta analyses of educational interventions studies (cont'd)

Study	Study's characteristics	Author(s)' findings
Brown 1992 [20] Reanalysis	***purpose:** to determine the influence of study characteristics, such as quality, and subject characteristics, such as age, on patient outcomes. ***inclusion criteria:** same as 1990 study except metabolic control was only based on measurements of glycosylated hemoglobin. 82 studies were reduced to 73 due to the restriction to glycosylated hemoglobin levels ***search:** same as 1990 study ***methodological quality:** used scoring scheme according to Sackett's and Haynes' model (1976). Total possible score 21. Two categories of quality were derived using median of 12, high quality =/>12 ***intervention:** same as 1990 study ***outcome measures:** knowledge composite (mean achievement scores in such areas as diet principles, insulin administration, pathophysiology); self care (weight loss and skill performance – insulin injection, self management techniques); metabolic control (restricted to glycosylated hemoglobin levels); psychological (locus of control, anxiety, coping, and attitudes) ***test for homogeneity:** conducted for each subcategory and outliers were excluded	*Study characteristics – weighted average ES related to each outcome. Published and unpublished – larger ES in unpublished studies for all outcome categories except psychological Research design – less rigorous designs consistently produced the larger effects except for psychological outcomes. *Quality of the study – higher quality studies produced larger effects for weight loss and lower effects for metabolic controls * Sample/setting characteristics – weighted average ES related to each outcome. Mean age of subjects (subdivided into three age groups – 25 to 39 years, 40 to 54 years, 55 to 68 years) ES estimates decreased for groups primarily over the age of 40 years with regard to knowledge. ES of diabetic education on glycosylated hemoglobin is lower in older patients. *Setting of educational intervention (inpatient and outpatient) – Hospital based programs produce larger effects for knowledge and metabolic control. Outpatient programs produce larger effects for weight loss and skill performance. *Types of diabetic treatment data reported inconsistently *Length of educational intervention (ranged from 5 min to 40 hr, shorter interventions 5 min to 6 hr and longer interventions 6.2 to 40 hr) longer interventions apparently foster greater learning as knowledge and skill performance outcomes yielded larger ES. Metabolic control did not differ according to length. Larger ES was associated with shorter interventions. *Length of follow up (divided into 3 categories – 1 mo, 1 to 6 mo, 7 to 12 mo). For knowledge and skill performance, ES of patient education increases over time. Degree of weight loss decreases to lower levels of effect within one yr. The pattern of glycosylated hemoglobin levels – data indicate an early moderate effect (0.46) with a peak from 1 to 6 mo (0.91) and a decline to earlier levels after 6 mo (0.5). Psychological outcome effects are the opposite with a decline at 1 to 6 mo and a return to earlier levels after 6 mo. *Overall the findings indicate that diabetes patient education is more effective in younger patients and metabolic control was only minimally improved by educational strategies in patient groups with mean ages of more than 55 yr.

APPENDIX D: PRIMARY QUANTITATIVE STUDIES

Table abbreviations

ADA – American Diabetes Association

BG – blood glucose

BMI - Body Mass Index

BP - blood pressure

CDCS - Comprehensive Diabetes Care Services

DCC – Diabetes Care Center

DEP - Diabetes Education Program

DES - Diabetes Education Service

DM - diabetes mellitus

F – females

FBG – fasting blood glucose

FHS – functional health status

GMH – Group Model Health Maintenance Organization

GP – general practitioner

hr(s) – hour(s)

HbA_1 - glycosylated hemoglobin

HbA_{1c} – glycated hemoglobin

HBGM – home blood glucose monitor

HC – health care

HDL – high density lipoprotein

HLOC – Health Locus of Control

HMO – health maintenance organization

IHD – ischemic heart disease

IHE – intensified health education

LA – Los Angeles

M - males

MI – myocardial infarction

min. – minute(s)

mo - month(s)
NE - Nurse Educator
NIDDM - non-insulin dependent diabetes mellitus
OHA - oral hypoglycemic agents
pts – patients
RCT - randomized controlled trial
QOL – quality of life
SMBG – self-monitoring blood glucose
WHO – World Health Organization
wk(s) – week(s)

Table 2: Primary studies on effectiveness of PDE

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Campbell et al. 1996 [23] Australia Prospective RCT Follow-up: 3, 6, 12 mo	N=238 pts, (124M/114F; aged 56-65 ys; treated: 34% by OHA, 63% by diet; 25% had upper high/tertiary education; all referred by physician) Inclusion: newly diagnosed NIDDM (for < 5 ys); aged <80 ys; understand, speak, read English; no previous formal instruction in diabetes care; no terminal disease; not taking > 75% of max dosage of OHA Pts remained under care of their GP, also may consulted a diabetes specialist (*not defined*) N_1=59 (Minimal Education); N_2=57(Individual Education); N_3=66 (Group Education); N_4=56 (Behavioral Program)	DEP (staff: 5 NE, 3 dietitians) to teach self-care (diet, exercise, urine/blood glucose monitoring, medication, foot care, visiting specialists); pts encouraged to bring a support person Minimal: total 40h; two 1-2hrs sessions (1 NE, 1 dietitian);same topics as other programs, less detail; Individual Education: two 1hr sessions (1NE, 1 dietitian), and approx. monthly 30 min. sessions until 12 mo from initial visit (with 1NE); same topics as other programs, more detail: causes, symptoms, mechanisms, complications; option for a 2-h lecture on diet (delivered to a group) Group Education: at least 2 individual sessions and a 3-day small group course (lectures, small group exercises, practical sessions; same topics as for other programs); individual sessions until group course established; 2-h group follow-ups at 3; 9 mo; option for a 2-h lecture on diet prior to course; 1 NE, 1dietitian, 1 podiatrist, 1occupational therapist Behavioral Program: cognitive-behavioral techniques (eating, exercise, smoking); emphasized cardiovascular risks; social support facilitated; individual home-based visits from 1 NE (not DE staff) at 3, 6, 12 mo, plus random phone calls; feedback loop of goal setting, contracting for behavioral goals, self-monitoring, problem-solving, renegotiations of goals established; emphasis on providing concrete specific advice; same topics	*no significant differences between Individual Education, Group Education and Behavioral Program groups in changes in knowledge, HbA_1, BMI, systolic BP, cholesterol levels *no significant differences between Individual Education, Group Education and Behavioral Program groups in proportion of pts visiting a podiatrist and an ophtalmologist, in proportion of pts who changed intensity of their treatment, or in terms of patient's satisfaction *Individual Education, Group Education and Behavioral Program groups groups did not differ in terms of mean number of visits made to a GP, proportion of pts who had hospital admissions *pts in Behavioral Program had greater reduction in diastolic BP than those in Individual and Group Education programs (p=0.022); *Behavior Program: significantly lower attrition rate than Individual and Group Education programs	*insufficient information on method for pt selection; *no information on pt's racial identification/cultural background, socio-economic status, complications *method of randomization not mentioned *no blinding *method used to diagnose NIDDM not mentioned *some differences in pts' characteristics between groups *some differences in pts' characteristics between drop-outs and pts with follow-up *pts in Minimal group followed up only for 6 mo; *programs not described in sufficient details (objectives, setting, methods, tools used for all programs; group size) *kind of payment not mentioned *conclusions on attrition based on pts who continued follow-up visits *appropriate role of DE not determined *no pts' educational need assessment *no information on educators' psycho-pedagogical background and type of training as a diabetes educator

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality

De Sonnaville et al. 1997 [29] The Netherlands Prospective controlled cohort study Follow-up: 1.5-2ys	Study group (SG):
	*2y follow-up data for 350 pts with known NIDDM (206 F/144M, mean age 65ys; diabetes duration 5.9 ys) and 95 with newly diagnosed NIDDM ("with onset within 3 mo"); all pts of 22 GPs in Amsterdam.
	*Inclusion: NIDDM known and newly diagnosed (WHO criteria), onset after 40 ys, treated for at least 6 mo with diet and/or OHA
	*23.1% drop-out rate during 2 ys follow-up
	Control group (CG):
	*1.5y follow-up data for 68 pts with known NIDDM (28F, mean age 64.6ys; diabetes duration 5.9 ys); all pts of 3 GPs in Amsterdam and 3 GPs in East of the Netherlands
	*33.3% drop-out rate during 1.5y follow-up
	*in the comparison, newly diagnosed NIDDM pts ("with onset within 3 mo") in SG were omitted since CG did not include any (comparable baseline characteristics except for gender, fasting glucose, BMI, HDL- cholesterol and BP)
		Diabetes Service System Amsterdam (DSSA): structured diabetes care, with DE (individual 30 min. sessions; diabetes nurse and dietitian; 2 follow-up assessments to repeat and check DE) and therapeutic advice according to a step-up treatment regimen (GP assisted by a lab with facilities to visit pts at home, a computerized pt register and recall system, a wide-angle retinal camera, possibility to consult a dietitian, a diabetes NE, a podiatrist)
		SG: glycemic control assessed at 3 mo intervals, annual review of complications, cardiovascular risk factors, assessment of well-being and treatment satisfaction; pts requested to measure fasting and pre-dinner glucose values (BG meters and insulin pens available in the Netherlands); incidence of hypoglycemia evaluated annually and in insulin-treated pts at least 3-monthly, at each visit or telephone call with NE (by HBGM)
		CG: pts seen at 3-mo intervals for glycemic control and annually for review of complications and cardiovascular risk factors; therapy titrated on basis of fasting BG level, aiming at 4.4-6.7mmol/l.; no fixed step-up regimen available for HBGM or insulin therapy; in an interview after 1.5 ys , pts asked if they had hypoglycemia
			SG vs. CG (only known NIDDM pts):
			*mean HbA1 fell from 7.4% to 7.0% in SG and rose from 7.4 to 7.6% in CG (p=0.004);
			*pts with poor control (HbA1c >8.5%): shifted from 21.4% to 11.7% in SG and from 23.5% to 27.9% in CG (p=0.008)
			*good control (HbA1c<7.0%): shifted from 43.4% to 54.3% in SG and from 54.4% to 44.1% in CG (p=0.013);
			*insulin therapy started in 29.7% of pts in SG and 8.8% of pts in CG (p=0.000) with low risk of severe hypoglycemia
			*mean levels of total and HDL-cholesterol, triglycerides in SG (p=0.000, p=0.004, p=0.012 respectively) and diastolic BP in SG and CG (p=0.000, p=0.01 respectively) and percentage of smokers in SG (p=0.003) declined significantly but prevalence of these risks remained high
			*BMI increased significantly in SG and CG (p=0.001, p=0.000 respectively)
			* in SG pts : general well-being didn't change significantly (p=0.36, p=0.49 respectively); treatment satisfaction not significantly changed but tended to improve (p=0.46, p=0.15 respectively); tendency to find diabetes management less demanding during study than before (p=0.06)
				*no information on known NIDDM pts' socio-economic status, level of education, co-morbidity, complications
				*majority of pts in both groups were of Dutch origin
				*no randomization
				*no blinding
				*DE not described in detail (not clear who instructed DE; objectives, methods, setting, tools, curriculum, type/number of follow-ups)
				*not clear whether CG pts had any DE
				*CG did not have newly diagnosed NIDDM cases (in comparisons, newly diagnosed NIDDM pts in SG omitted)
				*some differences in baseline pt characteristics between known NIDDM pts in SG and CG and between newly diagnosed and known NIDDM pts in SG
				*no comparison between characteristics of dropouts and those who completed follow-up
				*general well-being and treatment satisfaction evaluated only in 247 pts in SG who responded to questionnaires
				*role of DE was not determined
				*no pts' educational need assessment
				*no information on educators' psycho-pedagogical background and type of training as a diabetes educator
				*attrition rate for DE not discussed

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Peters & Davidson, 1998 [81] USA Prospective controlled cohort study Follow-up: 1-3 ys	CDCS group: N=97 DM pts (47.4%M; aged 26-79ys, diabetes duration 6.3 ys, 88 pts with type 2 DM; all referred by their physician, attended DE and enrolled continuously for 1y in CDCS after DE);17 pts did not complete 1y follow-up (not included in results) GMH group: N=67 DM (50.8% men; aged 23-78ys; diabetes duration 5.8 ys; 64 pts with type 2 DM; all attended a DE course at GMH); 10 pts did not complete 1y follow-up (not included in results) *in both groups: 40% Caucasians, 40% African-American, 15% Asian, 5% Hispanic; working-class population from LA	*CDCS program, using a computerizing tracking and recall system in conjunction with nurses (made clinical diabetes management decisions based on specific protocols for diabetes and lipid management) *DE course for both groups: were comprehensive (CDCS group meeting daily for 1 wk, GMH group meeting weekly for 4 wks); curriculum used was similar and followed ADA guidelines for DEPs *CDCS pts followed-up for compliance for 3 years *GMH had no standard follow-up care	CDCS group vs. GMH group: *HbA1c fell significantly in CDCS pts (from 11.9% to 8.8% at 1 y, and maintained for 3 ys of study) and were significantly lower than in GMH pts at 2 and 3 ys ($p<0.05$) *no significant changes in HbA1c levels in GMH pts *BP levels similar in both groups at baseline and throughout study *process measures (number of HbA1c levels and lipid panels per yr; number of foot or retinal exams) performed much more frequently in CDCS pts *no hospitalizations for acute diabetes-related problems in CDCS pts; 3 hospitalizations for diabetes-related problems in GMH pts *QOL (by SF-36) : no differences in non-diabetes-related parameters *overall diabetes-related QOL (2 diabetes-related questions): CDCS patients had a lower score (felt worse) at baseline than did GMH patients (felt better). The score improved in CDCS pts while the "sense of well-being" did not change in GMH pts over the course of study.	*inadequate description of pt selection and pts' characteristics *no randomization *no blinding *both groups included pts with type 1 and 2 diabetes, no separate reporting, no description of criteria used to diagnose them *no description of methods used to measure outcomes *no adequate description of DE (no details on any components) *some differences in baseline characteristics between groups *differences in insurance plans between groups *no pts' educational need assessment *no information on the educators' psycho-pedagogical background and type of training as a diabetes educator *role of DE was not determined *attrition rate for DE not discussed *diabetes-related QOL questions not used previously

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Domenech et al. 1995 [31] Argentina Prospective controlled study Follow-up: 1 yr	Inclusion: comparable socio-economic levels, received dietary advice (unstructured) from physicians, and/or treated with OHA Exclusion: newly diagnosed NIDDM, age over 60 ys, advanced micro-angiopathic complications, other severe diseases Intervention group (IG) *N=40 NIDDM pts (22F/18M, mean age 52.7ys; 29 on OHA; diabetes duration 6.9ys); dropout rate 25%; pts of 9 physicians (in program) Control group (CG) *N=39NIDDM pts (22F/17M, mean age 53.1ys, 32 on OHA; diabetes duration 6.3ys); dropout rate 55% ; pts of 9 physicians (comparable HC units; not in program)	*a teaching/treatment program (self-care, diet, physical activity and weight reduction rather than drug therapy) instructed by previously-trained physicians (2-day theoretical seminar) *program: 4 teaching units (90-120 min each) carried out once a wk for 1mo, in a group teaching setting (up to 8 ambulatory pts, encouraged to attend accompanied by spouse) *topics: unit 1(normal range for serum glucose, symptoms of hypo-/hyperglycemia, renal threshold for glucose, self-monitoring glycosuria with dry chemistry and record the value, recommendation to go on a low caloric diet and stop OHA intake for 1 wk); unit 2 (information and discussion on effect of obesity on insulin resistance; advantages of weight reduction; how to plan individual meals); unit 3 (foot care, physical activity); unit 4 (basic rules to be applied on 'sick days', minimal clinical and biochemical tests for control and follow-up) *tools: colored flip-charts, teaching files, photographs, question cards, individual log books for self-monitored data, questionnaire for evaluation and documentation of pt's diabetes-related knowledge before and after program	*mean differences in IG vs. CG were significant in weight loss ($p<0.01$), and number of daily OHA intake ($p<0.01$) but not significant in change/decrease of HbA1 levels * in IG pts, weight loss accompanied by diminution of OHA intake, HbA1 remained within acceptable range (9.1 ± 0.4% >7.5%) *in CG pts, weight loss not accompanied by diminution of OHA intake or by any overall change in HbA1 levels *performance of IG pts in diabetes-related knowledge test improved from 7 to 12 correct answers out of a possible 20 ($p<0.001$) *drop-out rate significantly lower in IG than in CG ($p<0.05$)	*inadequate description of study population, sample selection and specification *no randomization *no blinding *criteria used to diagnose NIDDM not mentioned *newly diagnosed NIDDM not defined *no comparison between characteristics of dropouts and those who completed follow-up *causes for drop-out in CG not identified *only IG pts tested for diabetes-related knowledge *no clear how many pts achieved good glycemic control (HbA1<7.5%) *no pts' educational need assessment *no information on educators' psycho-pedagogical background and no details on the type of training as diabetes educators *role of DE not determined/discussed

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Abourizk et al. 1994 [2] USA Prospective cohort study, with a comparison group Follow-up: 2, 4, 8, 12mo	Subjects: N=69 pts (mean age 51.7ys; 51% F, mean diabetes duration 99.8mo); all attended DCC (April'88-March'90) ; 50% drop-out *Inclusion: aged >18ys; on insulin; ; English-speaking; free of terminal disease, substance abuse, or severe mental health problems Comparison group: N= 54 pts (mean age 55.7 ys; mean diabetes duration 7.61 ys; 41% F; 11% on diet, 57% on OHA, 32% on insulin); adequate data to classify glycemic control; had diabetes; were seen over 12 mo at a HMO (Jan.'86-Jan.'88, outside DCC referral area); same inclusion criteria; sample included pts not on insulin	*4-day program, recognized by ADA, that includes: evaluation, treatment, individual sessions, meal selection, podiatry care, follow-up, opportunity to repeat all or part of program in future *reimbursable service which integrates education with treatment *pts with diabetes referred by their primary physicians, who continued to care for them *team: teaching nurses, endocrinologist or diabetologist, dietitian, podiatrist, social worker, exercise physiologist *short-term goal: improvement in metabolic control and functional status *long-term goal: maximum health free from complications of diabetes *reimbursable service, more than a program of mere didactic education *Comparison subjects had no formal DE during observation period	Subjects (with 8- or 12 mo follow-up): *HbA1 levels: fell from 9.97% to 7.53% ($p<0.01$) *FHS did not improve from baseline *relationship between knowledge and metabolic control differed for subjects with diabetes of short- and long duration (greater improvement in HbA1c in pts with shorter duration, not statistically significant) *predictor of improved HbA1c was baseline HbA1c *predictor of improved symptom score was race (Caucasians or Hispanics appeared to have greater improvement than Blacks) *no change in HLOC scores after attending *number of physician visits did not increase significantly Comparison group (mean follow-up 12.3 mo): *54% had worse glycemic control (increased HbA1 and fasting serum glucose), 43% improved and 3% showed no change	*both groups included type 1 and 2 diabetes, no separate reporting, no description of criteria used to diagnose *49/69 subjects (71%) completed follow up data on all study variables *no randomization *no blinding *in comparison group, data collected by chart review; no data on knowledge level, FHS, or HLOC *no adequate description of DE intervention (no information on number and duration of sessions, educational tools, setting; curriculum no adequately described; not clear how much time/attention spent with each topic; not clear what practical knowledge instructed) *role of DE not determined/discussed *no pts' educational need assessment *no information on educators' psycho-pedagogical background and type of training as a diabetes educator *attrition rate for DE not discussed

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Hanefeld et al. 1991 [53] Germany Multi-intervention RCT Follow-up: 2ys; 5ys	N=1139 newly diagnosed NIDDM pts(diet controlled); Inclusion: age 30-55 ys, diabetes controlled by diet, oral consent Exclusion: severe life limiting illness (myocardial infarction before entry, stroke, gangrene, cancer, other) Patients randomly assigned to: *Control group (CG): 378 pts (206M/172F; age 46.6y ± 5.6y; 251 non-smokers) *Intervention group (IG): 761 pts split into 2 groups: (IHE)group 382 pts (231M/151F; age 46.2y ± 7.0y) who received IHE and placebo (IHE+CC) group : 379 pts(198M/181F; age 45.8y ± 8.8y) who received IHE and 1.6g clofibric acid (CC) per day *1008/1139 pts completed the study (88.5%)	*during follow-up, CG was cared for at a different local diabetes clinics with a standardized surveillance (trained diabetologists; same timing of visits for IG pts, strict adherence to prescriptions with fix cut off limits for drug use not ensured; regular clinical check ups with 3-4 monthly visits; traditional diet, rigid with regard to timing and amount of carbohydrate intake, following the recommendations by the Medical Council for Diabetes Research) *IG had a structured intensive health education (IHE) that also included dietary advice and instruction about diabetes management; antismoking and antialcohol education; ways to enhance physical activity; IG pts had clinical investigation (medical history, smoking habits, drug intake, hospitalization, major illness, symptoms of angina pectoris and peripheral arterial disease, side effects of clofibric acid); pts were seen at entry and at 5 year follow-up *Details of study design, methods, epidemiological data at entry published previously	*antidiabetic drugs used by 47% CG pts; 34% (IHE+CC) pts; 28% (IHE) pts, ($p<0.01$) *weight stable in all 3 groups *adjusted FBG levels improved significantly in IG pts vs.CG pts ($p<0.01$) *no significant difference in levels of glucose control between IG groups *similar significant increase in cholesterol levels in all 3 groups *efforts to reduce overnutrition and fat consumption failed in all groups *both ratio of pulyunsaturated to saturated fatty acids (0.26 in CG vs. 0.41 in IG, $p<0.01$) and physical activity (174 scores in CG vs. 327 scores in IG, $p<0.01$) increased *BP, tobacco, alcohol consumption significantly reduced in IG pts vs. CG pts ($p<0.01$) *completion rate: 91.5% in CG, 85.9% in (IHE), 88.1% in (IHE+CC) *no statistically significant difference in cardiovascular complications rate (incidence of MI and IHD in the first 5ys after diagnosis) among groups *death rate per 1000 was 46.2 in CG, 30.6 in (IHE) and 27.0 in (IHE+CC)	**insufficient descriptive data on pts *method of randomization not specified *only benefit of clofibric acid was evaluated in a double blind study * programs not described in sufficient details (core team, methods and tools, mode of follow-up, setting, curriculum, duration/type/frequency of sessions) *no pts' educational need assessment *no information on educators' psycho-pedagogical background and type of training as a diabetes educator *not clear who the educator is for the intervention group *measures used for evaluated outcomes not sufficiently described *pts in IG used more intensively antihypertensive drugs *by a random error, pts in CG had significantly higher fasting BG levels at entry than pts in both IGs *

Table 2: Primary studies on effectiveness of PDE (cont'd)

Study	Study population's characteristics	PDE's characteristics	Reported outcomes (over 12 mo)	Comments on methodological quality
Glasgow et al. 1996 [45] USA RCT Follow-up: 12 mo	N=206 adults with known diabetes (with moderate education and occupation levels; 78% had type 2 DM, 67% were on insulin, most had high cholesterol levels, a variety of medical problems and diabetes for over 10 ys) attending an internal medicine outpatient clinic Inclusion: type 1 or type 2 DM, age 40ys or older, being primarily responsible for own diabetes dietary self-management) All pts randomized to: *Usual Care (UC) group with n=94-98 pts (63% females; 76% type 2 DM; mean age: 61.7 ys) *Brief Intervention (BI) group with n=106-108 pts (60% females; 81% type 2 DM; mean age: 63.1 ys) *no follow-up at 12 mo in 16% of pts	All pts completed a 4-day food record form and a background information and had a baseline assessment (overview, measurement of height, weight, total cholesterol and HbA1c levels, computerized touchscreen assessment, and Food Habits Questionnaire) UC group: high quality quarterly medical care intervention (regular assessment, follow-up of micro- and macrovascular risk factor, and touchscreen computer assessment) but no focus on behavioral or psychosocial issues related to dietary behavior BI group: personalized, medical-office-based intervention focused on behavioral issues related to dietary self-management (single session intervention, involving 5-10 min. touchscreen computer-assisted assessment , with immediate feedback on key barriers to dietary self-management, 20 min personalized goal setting and problem-solving counseling, and dietary self-help materials); follow-up components: phone calls (1-3wks to review progress, provide support, mail videotape and written maintenance information), and 30 min. interactive videotape intervention relevant to each participant; required 2 min. of physician time and 1-2 h of allied health professional time per patient over 1 yr.	*significant greater improvement on multiple measures of change in dietary behavior in BI group vs. UC group (p=0.023) *significant reduction in serum cholesterol in BI groups vs. UC group (p<0.002) *no significant differences or improvements on either HbA1c or BMI between groups *significant differences on "patient satisfaction with medical visits" in favor of BI group when compared to UC group (p<0.02) *costs of BI ($137/pt) were modest relative to many commonly used practices (not described) *attrition rate: 16.7% in BI group vs. 15.3% in UC group	*no blinding *no information on diagnostic criteria *no sufficient description of the educational/counseling intervention (core team, objective, strategy, methods, content, setting) *no information on health educators (professional and psycho-pedagogical background and type of training as diabetes educators) *no specific goal of the project *the dietary barrier scale and measures for patients' satisfaction developed by authors and not clear whether validated *dietary measures relied on food records self-reported by pts *included both type 1 and type 2 diabetes but no separate reporting *the role of DE/counseling intervention not determined

APPENDIX E: SYSTEMATIC REVIEWS

DM – diabetes mellitus

DSM - diabetes self-management

DSME – diabetes self-management education

GHb – glycosylated hemoglobin

HbA1c – glycated hemoglobin

QOL – quality of life

RCT – randomized controlled trial

SMBG – self-monitoring blood glucose

UK – United Kingdom

USA – United States of America

Table 3: Comprehensive and systematic reviews

Study	Study's characteristics	Study's main findings/recommendations
Albano et al. 1998 [5] Italy and Switzerland	*literature review of 37 RCTs cited by MEDLINE (1986-April 1996) to evaluate their descriptions of the educational approach used *requested criteria: randomization *keywords: diabetes, patient education, randomized *papers analyzed by using a check list of 27 items grouped in: study objectives, educational objectives, population, educational strategies, content, evaluation, outcome, final results	The analysis shows a poor description of all elements of the educational programs in the reviewed RCTs. Their authors focus their attention on very few aspects of diabetes. Educational programs deal with very specific aspects of diabetes instead of taking into account a broad range of areas concerning the disease. Researchers indicate the content of the program rather than mentioning realistic educational objectives and relating their pertinence to the patients' needs. Editors should request RCTs containing information on identification of patients' needs, elaboration of learning objectives, planning and running of the program and the evaluation system used.
Clement, 1995 [26] USA	*review of articles published in peer-reviewed journals, grouped into long-term (>12 months) prospective RCTs, studies addressing hospitalization rates, studies addressing cost-effectiveness of self-management education, short-term (<12 months) RCTs, randomized or non-randomized studies *objectives not mentioned *no information on the literature search and strategy *no information on methodology *diabetes self-management education (DSME) is defined as the process of providing the person with diabetes with the knowledge and skills needed to perform self-care, manage crises, and make lifestyle changes required to successfully manage the disease	When coupled with timely and appropriate adjustment of medication DSME is associated with a reduced morbidity and possibly reduced mortality. To help reduce the health care costs of diabetes by reducing short- and long-term complications DSME programs must incorporate the following guidelines: *the interventions must make intensive use of behavior change strategies *the intervention must be appropriately matched to the needs and abilities of the patient *the personnel must work closely with the patient's health care provider as part of an integrated team. Studies are needed to determine predictors that identify which patient will benefit from which type(s) of DSME program. The optimal interval for follow-up needs to be determined for any patient group and to be tested. Innovative strategies for helping patients overcome physical, social and psychological barriers to adherence are needed.

Table 3: Comprehensive and systematic reviews (cont'd)

Study	Study's characteristics	Study's main findings/recommendations
Vijan et al. 1997 [105] USA	*literature review to summarize current knowledge on screening, prevention, counseling and treatment of complications used for care of type II DM patients *literature identified through consultation with experts and a focused MEDLINE search (January '76-December '96) *keywords: diabetes mellitus, non-insulin-dependent, retinopathy, neuropathy, nephropathy, hypertension, lipids, triglycerids, low-density lipoprotein, smoking, blood glucose, foot care, self-management, education, preconception care, prevention, treatment, control, *experimental and observational studies with sample size > 30 patients, follow-up >3 mo (clinical trial, controlled clinical trial, RCT, cohort studies, multicenter trial, meta-analysis) *articles were critically reviewed and evaluated by each author (*methodology was not mentioned*), and recommendations for diabetes care was reached by consensus discussion of available evidence	At the time DM is diagnosed, the patient should be given extensive information about the disease, and its management, including the importance of self-management. Self-management education is most effective when presented in collaboration with a provider. An important part of the provider's role is to review and update the information the patient needs to manage the disease, ascertain the extent to which the patients is managing the disease appropriately, reinforce self-management behaviors and refer to diabetes education programs or nutritionists. Important topics include: active responsibility, glucose goal, SMBG, medications, exercise, meal plan, stress and coping, questions answered, emergency situations, diabetes identification, complication screening, foot care, injection sites. Any topic may be important at any visit, based on patient- and provider-identified needs. There is no scientific evidence that the brief discussions on these topics will lead to improved outcomes. However, these topics represent content areas that have been identified as necessary to meet standards for diabetes care.
Glasgow et al. 1996 [45] USA	*mini-review of research on DSM published in *Diabetes Care* or *The Diabetes Educator* between 1990 and 1995 *included: studies concerned with producing lasting changes in patient behavior or outcomes (with > 5 participants) *excluded: lab studies on transitory acute effects of exercise; studies focused solely on pharmacological rather than educational interventions *to document the continuing neglect of issues of representativeness (specifically participation and attrition) and present the use of a framework for how such factors can be analyzed	There has not been improvement since 1980s in the percentage of studies that report on participation. Most studies now report on attrition. Future DSM research should report on both attrition and participation in a standard manner. It is recommended to: 1. Describe the population, eligibility criteria, recruitment procedures 2. Report on participation rate (conservatively defined) 3. Identify characteristics of participants vs. non-participants 4. Report attrition rate by condition at each follow-up assessment 5. Analyze relationship of subject characteristics and treatment condition to attrition

Table 3: Comprehensive and systematic reviews (cont'd)

Study	Study's characteristics	Study's main findings/recommendations
McLeod, 1998 [67] Canada	*literature review of papers to identify trends in DE research since late 1980s till present and provide guidance for conducting DE research in future (MEDLINE, ERIC, Dissertation Abstracts; 1987-1997) *keywords: diabetes education, evaluation, outcomes, metabolic control, behavior, self-care and learning resources *after review of abstracts, concepts included for review: outcome measurement, quality of life, adherence and decision making	Research in DE has progressed immensely and helped education programs to continue to improve services. However, there are some identifiable areas or "gaps" that require further study: • Theories such as personal models, goal-setting, decision-making and problem-solving; • Development of standard definitions and reliable instruments for measuring adherence and QOL; • And the education process, which includes descriptions of the types of interventions used and the effects of these on diabetes management, longitudinal studies on learning process and alternative approaches to education. There is concern in relation to the diabetes educators' lack of knowled about the research process, lack of support for research activities and constraints.
McIntosh et al. [73] Forthcoming (*informed "Effective Health Care" bulletin, March 2000, vol. 6, no. 1, by University of York)* UK (NHS CRD)	*review on the effectiveness of patient education in the management of type 2 diabetes *RCTs and systematic reviews identified by searches in 10 databases (*databases, search strategy, keywords were not identified in bulletin)* *professional education and interventions concerned with foot care, retinopathy, screening and renal care were not included *two reviewers assessed studies for relevance independently and data were extracted by at least reviewers independently; discrepancies resolved by discussions the quality of studies was assessed; analysis was by qualitative synthesis	Long-term benefits of interventions designed to promote self-management of type 2 diabetes have yet to be demonstrated. Although many programs produce desirable outcomes in the short-term and reduced HbA1c levels, these need to be sustained to produce health gains. People with type 2 diabetes should be encouraged to be involved in their own care. Interventions should be appropriate to individual characteristics and should take into account factors such as age, educational level, and ethnic origin. Further research is necessary to determine whether interventions to promote self-management of type 2 diabetes have positive and clinically significant long-term effects on outcomes such as weight and HbA1c levels. Trials need to measure morbidity and quality of life outcomes, and if possible, mortality as well as "surrogate" outcomes.

Table 3: Comprehensive and systematic reviews (cont'd)

Study	Study's characteristics	Study's main findings/recommendations
Glasgow & Osteen, 1992 [47] USA	*literature review of published studies on diabetes education included in the Brown's meta analysis (1990) *to discuss the frequency of use and quality of measures that have been collected within each of the categories: 1) environmental and social context of program; 2) characteristics of participants; 3) process and mediating variables; 4) diabetes management; 5) short-term health outcomes; 6) long-term health outcomes *makes recommendations for outcome measures to be used in future research	Program evaluations to date have focused to narrowly on assessing knowledge and GHb outcomes to the exclusion of other important variables. To reflect the changing emphasis and conceptual basis of diabetes education, it is recommended that future evaluations do the following: 1) Report on program's target population, recruitment methods, and representativeness of participants 2) Collect measures of self-efficacy and patient-provider interactions 3) Include quality of life and patient-functioning outcome 4) Use more standardized and objective measures of diabetes management behaviors

APPENDIX F: CANADIAN STUDIES

Table 4: Canadian Studies

Study	Sample characteristics	PDE's characteristics	Reported outcomes	Author's conclusions
Tildesley et al. 1996 [95] British Columbia Program evaluation	N = 5,823 pts from 1985-1995 Group 1:1,067 pts; IDDM; 37ys(±12.8ys); 54% M; disease duration 16ys(±13.2) Group 2:1,192 pts; diet treated NIDDM; 56ys(±12ys); 56%M; disease duration 4ys(±4ys) Group 3: 2,269 pts; oral agent NIDDM; 60ys(±12ys); 59%M; disease duration 8ys(±6ys) Group 4: 1,295pts; insulin treated NIDDM; 60ys(±11ys); 52%M; disease duration 15ys(±8ys)	*multidisciplinary team: nurses, dietitians, physicians, social worker * core program: 4 consecutive days or evenings; all meals eaten at the centre; tests taken before meals and before departure from the centre; seen daily be endocrinologist; contact with family doctors usually by phone; taught self HBGM; * Follow up(FU) at 3 mos, 6 mos and then yearly for 1 day condensed version of core program; at each FU complete questionnaire evaluating program and staff	Data provided at initial visit and at 6ys Group 1: HbA1c 0.092 and 0.087; % ideal body weight(IBW) 1.04 and 1.08 (SS); hypoglycemic episodes per mo 6.7 and 5.8; HBGM per wk 12.7 and 14.8 (SS) Group 2: HbA1c 0.077 and 0.071; % IBW 1.23 and 1.16 (SS); HBGM per wk 1.6 and 4.7 (SS) Group 3: HbA1c 0.086 and 0.081; % IBW 1.20 and 1.17 (SS); HBGM per wk 3.36 and 5.8 (SS) Group 4: HbA1c 0.095 and 0.085; % IBW 1.19 and 1.18;; HBGM per wk 6.3 and 10.6 (SS)	On average patients performed significantly more HBGM/week and gained significantly improved glucose control
Basa & McLeod, 1995 [10] British Columbia Program evaluation	N=49pts (10pts lost to FU, reasons provided) Inclusion criteria: NIDDM diagnosis, fluent in English at grade 8 level, no DEP in last 5ys; consent to complete all questionnaires over 6 mo FU N=39pts (13 diet controlled; 22 diet and OHA, 4 diet and insulin) 52ys; 22 M	*outpatient clinic, all pts referred and assessed by team *multidisciplinary team: medical diabetes specialist, nurse, dietitian (physiotherapists, social workers & pharmacists available if necessary) *program dependent on need – individual FU or 2 day program *Individual sessions: 1 –2 hrs *Education program: basic self learning skills (SMBG, insulin administration, meal planning, exercise, foot care); basic physiology of diabetes; complications; adjustments to maintain glucose control;10 hrs	Data collected at entry, after education session, 3 & 6 mos Knowledge (developed by Michigan Diabetes Research and training Centre): 71.7 (±13.0) to 80.4 (±10.8) at 6mo SS at all 3 FU periods Quality of life (16 statements, 5 point Likert):39.6(±8.4) to 57.8(±10) at 3 mo SS Emotional adjustment (ATT39): 14.9(±10.6) to 21.2 (±11.1) at 3 mo SS HbA1c: 8.8(±2.2) to 7.1(±1.2) SS at 3 mos and 7.1(±1.3) SS at 6 mos	Program evaluation should include the assessment of lifestyle adjustments and the emotional impact of diabetes on the individual. Clients perceived that medical management rather than education was primary function of the centre.

Table 4: Canadian Studies (cont'd)

Study	Sample characteristics	PDE's characteristics	Reported outcomes	Author's conclusions
Tilly et al. 1995 [97] Ontario Program Evaluation	N=1155 total number admitted October 1991 to December 1992. Eliminated children <15ys, pts with gestational diabetes, pts just starting insulin, those without a complete data set N=355 (167 pts returned to the clinic for 6 mo FU, 188 completed FU questionnaires by phone); 320 Type 2; average age 53.3 ys;	*Outpatient service, pts referred *multidiscipline team (certified diabetes educators – nurse, dietitian) *Individual session lasting 90 to 120 minutes provided basic education (meal planning, diabetes management skills, personal behaviour change strategies). Pts could chose FU individual sessions and/or group classes (Senior Class (1 day), Day class(2 days), Evening Class(3 evenings)) *All pts asked to attend 6 mo FU session with nurse and dietitian	Data collection questionnaires administered at admission & 6 mo FU by phone or in clinic Health status outcomes measured by: HbA1c, diabetes related quality of life (TyPE Specification), general quality of life (SF36) HbA1c: values for 71/355 pts available, average decrease 1.2% SS 33/71 newly diagnosed pts dropped from 9.4% to 7.5% 38/71 10.1 ys disease duration dropped from 9.7% to 9.1% TyPE Specification: SS improvement in decreased frequency of diabetes related symptoms SF36: SS increase in functional status (6 of 8 scales improved)	HbA1c did not correlate with any of the health related quality of life scales. Newly diagnosed pts showed significant reduction in HbA1c than did pts with a history of diabetes. Study demonstrated the value of multidimensional approach to outcome assessment and program evaluation.
Fiala & Gaizauskas 1994 [37] Ontario Program Evaluation	N=26 pts (12/26 in pilot group); 25-72ys; 24Type 2; 5M; 11 diet; 10 OHA; 5 insulin Inclusion criteria: DM; BMI >27; want help in reducing weight & BG	*prior to start of program each pt saw dietitian to design individual meal plan *Healthy Weight Program1 hr output sessions for 10 wks; nurse & dietitian provided general information on diabetes & specific nutritional advice & exercise; elective post meal BG and weigh-ins; variety of activities & teaching tools used *All invited to 3 mo post program which included discussion on healthy eating, barriers encountered & strategies to overcome barriers; weight & BG values	BMI: wk 1 27 to 54 (mean 35 ± 6.1) wk 10 (mean 34 ± 5.5) SS weight change ranged from +0.9 to –10kg (av loss 2.8kg) HbA1c: pre 0.088 ± 0.02 & post 0.07 ± 0.012 (23/26) SS 14/26 at 3 mo FU: 5 continued wt loss; 3 maintained wt loss; 6 regained wt loss	Increased understanding and adherence to diabetes meal plan resulted in an average weight loss of 2.8 kg and 40% increase in pts with acceptable BG control. Lifestyle education in small groups has beneficial effects on BG control in the short term1

Table 4: Canadian Studies (cont'd)

Study	Sample characteristics	PDE's characteristics	Reported outcomes	Author's conclusions
Mickus & Quaile 1997 [68] Ontario Program evaluation	N=242 pts self referred or physician referred for 1993 calendar y; 21 to 90 ys (mean 58.2ys); 118M;51% completed some or all high school; disease duration 5.2ys; 42% newly diagnosed; 75% no previous diabetes education; 62% OHA	*Outpatient 3 day course over 1 week offered to groups no larger than 8 who were self referred or referred by physicians; mixture of lectures and interactive discussion about causes and symptoms of diabetes, physiological changes associated with disease, lifestyle changes and nutritional requirements. *Before class pts completed a knowledge questionnaire; information on SMBG, height, weight, medication, usual food and activity patterns *after classes knowledge questionnaire completed *FU at 2wks, 2.5mos,6.5mos & 1yr with nurse and dietitian	88% (213/242) completed the PDE program and attended the FU at 2wks; 37% (88/242) attended the 12.5 mo FU Outcome measures reported at each FU: knowledge scores; BG; HbA1c; number and doses of medication; HBGM(yes/no); activity level(# of times and hours/wk); Analyses of differences between initial measure and measure at any one of the last FU visits. *Due to high drop out rate results are not documented here*	HbA1c, BG, BMI & weight loss showed improvements at initial stages of program monitoring but subsequently declined over time Pts last documented outcome performance score for each of the 8 outcomes significantly improved from initial program scores
Thompson et al. 1999 [94] British Columbia RCT	N=46 randomly assigned by sealed envelop Standard care = 23; 11 type 2; mean age 50 ± 14.8 yr; 11F; mean disease duration 19.2 ± 7.9 yr; mean duration of insulin therapy 13.7 ± 8.4 yr. Telephone care = 23; 9 type 2; mean age 47.5 ± 11.8 yr.; mean disease duration 14.7 ± 9.2 yr; mean duration of insulin therapy 10.2 ± 8.9 yr. Inclusion criteria: receiving insulin, able to monitor BG at home, had standard diabetes education, HbA1c =/>0.085, FU at centre Exclusion criteria: inability to communicate, by phone, use of insulin pump or other serious disease	Standard care: continued regular clinic visits, HbA1c every 3 mos Telephone contact: frequency and duration of telephone contact with nurse was individualized, av 3 calls/wk for 15 minutes, insulin adjusted during call *nurse reviewed pt charts with pt's physician every 2 wks	Standard care: HbA1c 0.094 ± 0.008 initially and at 6mo 0.089 ± 0.010 NSS Mean body wt 76 kg(16) initially-no wt gain at 6mo Telephone contact: HbA1c 0.096 ± 0.01 initially and at 6mo 0.078 ± 0.008 SS 20 pts had a decline in HbA1c of at least 10% Mean body wt 77(14)kg initially 4kg wt gain at 6 mo	Insulin adjustment according to advice from a diabetes nurse educators an effective method of improving glucose control in insulin requiring diabetes pts

Table 4: Canadian Studies (cont'd)

Study	Sample characteristics	PDE's characteristics	Reported outcomes	Author's conclusions
Vallis 1997 [103] Nova Scotia Prospective non-randomised comparison of extreme groups	N=22 participants, categorized into 2 grp - Strongly non adherent =15; 8 Type 2(3 required insulin);5 males; 7 married; 12.3 yrs educ; mean age 39.9; duration of disease 10.3yr; mean BMI 29.4 Strongly adherent = 7; 5 Type 2(1 required insulin); 2 males;6 married; 11.8 yrs educ; mean age 50.7; duration of disease 5.6yr; mean BMI 23.7 Inclusion criteria: well known to staff; identified by staff as strongly adherent or strongly non adherent Categorization into groups: used rating form assessing 3 behavioural categories -diet (administered by dietitian), self monitoring & medication/insulin usage (administered by nurse)	Not applicable	Group validation by comparing HbA1c and self reported adherence using Diabetes Behaviour Questionnaire & Self-reported Adherence Scale developed by the author Adherent grp: HbA1c 6.53 ± 0.38 Non adherent grp: HbA1c 9.12 ± 1.38 Psychosocial assessments included: diabetes adjustment scale (diabetes specific quality of life measure-impact, satisfaction, worry); barriers to adherence questionnaire (diet, self monitoring exercise); health beliefs questionnaire (cues to adherence, benefits to adherence, perceived severity, perceived susceptibility, cost of adherence); diabetes family behaviour checklist (supportive, non supportive behaviours); diabetes knowledge and management skills assessment	Duration of disease & mean BMI were SS between grps Three scales significantly differentiated adherence from non-adherence: health belief (perceived benefits of adherence), quality of life (emotional impact of diabetes) and barriers to adherence (diet) These 3 factors correctly classified all but one of the non-adherent participants. Non adherent grp greater barriers to adhere to diet, fewer benefits to adhere and emotionally negatively affected. Not significant but showed a trend for non adherent to know more about the principles of diabetes care Non adherent would benefit from psychosocial intervention on emotional, cognitive and problem solving aspects of diabetes care

Appendix G: Details on Canadian Studies

Program Evaluations

Tildesley et al [95] reviewed outcome data on 5,823 patients who returned to St Paul's Hospital, Vancouver, BC over a period from 1985 to 1995. The program is managed by a multidisciplinary team (dietitians, nurses, physicians, social worker). During the four consecutive days or evenings of the 'core' program, all meals are eaten at the centre. Each person is taught self blood glucose monitoring and tests are taken before meals and before departure from the centre. During the core program patients are seen daily by an endocrinologist and are in contact with family doctors usually by phone. Newly diagnosed patients are requested to return 3 months after attending the core program for a one day follow up. Follow up is encouraged at 3 months, 6 months and then yearly for a one day follow up which is a condensed version of the 'core' program. At the end of each follow up visit patients are requested to complete a questionnaire evaluating the program and the staff. Patients were categorized into four groups for analysis:

- Patients with insulin dependent diabetes 1,067; age 37 (± 12.8 years); duration of disease 16 (± 13.2 years); 54% males (Group 1).
- Diet treated NIDDM patients 1,192; age 56 (± 12 years); duration of disease 4 (± 4 years); 56% males (Group 2).
- Oral agent treated NIDDM patients 2,269; age 60 (± 12 years); duration of disease 8 (± 6 years); 59% males (Group 3).
- Insulin treated NIDDM patients 1,295; age 60 (± 11 years); duration of disease 15 (± 8 years)); 52% males (Group 4).

Data were provided on HbA1c, % ideal body weight, and home blood glucose monitoring per week for all four groups. Hypoglycemic episodes per month were provided for the IDDM group only. Outcome data was reported on 6 years of follow up for all four groups:

- Group 1 initial HbA1c 0.092 and at 6 years 0.087; % IBW 1.04 and 1.08; hypoglycemia episodes 6.7 and 5.8; glucose monitoring 12.7 and 14.8 times per week at 6 years.
- Group 2 initial HbA1c 0.077 and at 6 years 0.071; % IBW 1.23 and 1.16; glucose monitoring 1.6 and 4.7 times per week at 6 years.
- Group 3 initial HbA1c 0.086 and at 6 years 0.081; % IBW 1.20 and 1.17; glucose monitoring 3.36 and 5.8 times per week at 6 years.
- Group 4 initial HbA1c 0.095 and at 6 years 0.085; % IBW 1.19 and 1.18; glucose monitoring 6.3 and 10.6 times per week at 6 years.

All groups performed significantly more monitoring of blood glucose levels per week over the 6 years and HbA1c levels improved. The downward change in percentage IBW in the Group 2 and 3 was significant. Significant improvement in diabetes control without an increase in hypoglycemic events in Group1 but a significant upward trend in %IBW was noted. The authors conclude that there is a positive correlation of knowledge with outcome measures, that on average patients performed significantly more home monitoring and gained significantly improved glucose control.

Basa and McLeod [10] conducted a study to evaluate the effectiveness of the education program to improve metabolic control and quality of life for patients with NIDDM, at the Diabetes Specialty Centre, Vancouver, BC. This is an outpatient adult diabetes clinic providing multi disciplinary care (medical diabetes specialist, nurse, dietitian) with physiotherapists, social workers and pharmacists available if necessary. All patients were referred by the family physician and on their initial visit were individually assessed by the team. Patients may return for individual follow up or attend a 2-day education program depending on their need. The education program included basic self-learning skills and was approximately 10 hours in duration. The individual sessions were 1 to 2 hours in duration. Patients had to meet the following inclusion criteria - diagnosed with NIDDM, fluent in English at the grade 8 level, had not attended a formal education program in the last 5 years, and consented to the study and completed all the questionnaires over the 6 month follow up period. Forty-nine patients were eligible but only 39 completed the four required visits. Reasons for those lost to follow up were provided by the authors. The 39 participants were on average 52 years of age and 22 were males. Thirteen were controlled by diet alone, 22 by diet and oral medication and 4 by diet and insulin. Data were collected on knowledge, emotional adjustment or attitude (ATT39), quality of life (5 point Likert) and HbA1c, at entry into the program, after the 2-day education session, and at 3 and 6 month follow up visits. The mean knowledge score was significantly ($p<0.05$) higher (6 months 80.4 ± 10.8) than the initial score (71.7 ± 13.0) at all 3 follow up measures. Both the mean quality of life score (baseline 39.6 ± 8.4 at and 3 months 57.8 ± 10) and ATT39 scores (baseline14.9 ± 10.6 and 3months 21.2 ± 11.1) were significantly ($p<0.05$) better at 3 months. HbA1c levels were significantly ($p<0.05$) lower at 3 months (7.1 ± 1.2) and 6 months (7.1 ± 1.3) than at baseline (8.8 ± 2.2). All participants both before and after the program agreed that they were fully responsible for their care and management of diabetes. Patients attending the program perceived that the primary function of the centre was medical management rather than education. Authors note that improvement in quality of life should be one of the primary goals of a PDE.

Tilly et al [97] conducted an outcomes management project to evaluate a PDE an outpatient service located at Peel Memorial Hospital, Brampton, Ontario. The

three main categories of health status outcomes measured included HbA1c, diabetes-related quality of life (TyPE Specification), and general health related quality of life (SF-36). The first initial individual session comprised a basic educational intervention that lasted 90 to 120 minutes and was provided by a multidisciplinary team (nurse and dietitian). Three group classes were offered. All patients were requested to attend a follow up session at 6 months. Data collection questionnaires were administered at the time of admission and at 6 month follow up by phone or in the clinic. A total of 355 patients (320 Type 2 diabetes) with an average age of 53.3 years participated in the study (one group pretest-posttest design). Two hundred and sixteen patients attended additional sessions. HbA1c was available for only 71 patients due to criterion dates (HbA1c needed to be obtained within ±30 days of questionnaire dates). However these patients did not differ on initial HbA1c or any independent variables from excluded patients. The patients improved significantly in all categories of outcome – the average decrease in HbA1c was 1.2%, frequency of diabetes symptoms was reduced and overall functional status and well being improved. The authors note that HbA1c did not correlate with any of the health related quality of life scales either initially or at 6 months. Newly diagnosed patients (33 patients <1year) showed significant reduction in HbA1c compared to patients (38 patients mean 10.1 years) with a history of diabetes. Initially the HbA1c was the same in both groups but dropped from 9.4% to 7.5% in the newly diagnosed group compared to 9.7% to 9.1% for the others. A significant portion of the main effect for HbA1c appeared to be due to the large decrease of HbA1c levels in the newly diagnosed patients but the analysis of the health related quality of life variables showed no effect of duration. The authors note that although the results were positive they could not conclude with certainty that the PDE was the cause.

Fiala and Gaizauskas [37] reported on the outcome of a 10 week Healthy Weight Program managed by a nurse and dietitian at the Peel Memorial Hospital, Brampton Ontario. This program provides behavioural and nutritional information to help patients make lifestyle changes that will result in weight loss and improved blood glucose control. Participants were invited to a three month post group meeting to discuss healthy eating, barriers encountered and strategies to overcome the barriers. The results on the first two groups of patients (12 and 14 participants) who attended the program are reported. The patient inclusion criteria included anyone with diabetes mellitus, a BMI greater than 27 and those who wanted to have help in reducing weight and improving blood glucose control. Participants ranged in age from 25 to 72 years; 21 females; 24 had type 2 diabetes; 11 were treated with diet alone; 10 were on oral medication; and five were being treated on insulin. HbA1c levels and weight were compared pre- and post-program. The BMI ranged from 27 to 54 (mean 35 ± 6.1) at week one to a mean BMI of 34 ± 5.5 at week 10, which was a statistically significant change. Mean pre HbA1c levels were 0.088 ± .02 and post HbA1c levels were 0.07 ± .014

for 23/26 participants and was a statistically significant improvement. Fourteen participants returned for the 3 month follow up meeting. Of these, five continued to lose weight, three maintained weight loss and six regained the weight loss. The authors concluded that the Healthy Weight Program in a small group setting has beneficial effects in the short term on weight loss and on blood glucose control.

Mickus and Quaile [68] conducted a retrospective chart review of 242 participants to evaluate the extent to which participation in the outpatient PDE at the Grace Hospital, Ottawa, Ontario led to improvement in self-management and knowledge. Participants were self-referred or were referred by a physician, had a mean age of 58.2 years and 118 were male. The education program was a three day course over a week offered to groups of no larger than eight. Four follow up appointments with a nurse and dietitian were scheduled at 2 weeks, 2.5 months, 6.5 months and one year. A diabetes knowledge questionnaire was completed immediately before the PDE, and at all follow up periods. Outcome measures, besides the knowledge scores, included blood glucose levels, HbA1c levels, number and dosage of medications, weight, BMI, home glucose monitoring (yes/no), activity levels (number of times per week). 88% (213/242) completed the PDE and attended the first follow up at 2 weeks. Only 37% (88/249) of the participants attended the one year follow up. No significant differences were found regarding age, gender, number of years diagnosed with diabetes, education, achievement, language, prior diabetes education, prescribed medication, physiologic and metabolic readings and exercise patterns between the 213 who attended at least one follow visit and those 29 who did not. Participants ranged in age from 21 to 90 years (mean 58.3 years, gender evenly distributed, 62% were taking oral medication and the average number of years since diagnosis was 5.2. The results for each of the outcome measures were reported on the analysis of differences between the initial measure and the measure at any of the last follow up visits (2 weeks, 2.5 months, 6.5 months or one year). Results showed that the participants' last documented outcome performance scores for each of the outcomes measured were significantly improved from their initial scores. The authors expressed their concern at the loss of participants over the monitoring period.

Other studies

Thompson et al [94] undertook a study in BC to determine if the addition of insulin adjustment provided by phone through a nurse educator could lead to better glucose control (measured by HbA1c) in insulin requiring patients with poor glucose control. Patients were eligible if they were receiving insulin; able to monitor blood glucose levels at home; being followed up; and under the care of an endocrinologist. Additionally, they had to have undergone standard diabetes care at the hospital clinic and their most recent HbA1c level was 0.085 or higher. Charts of patients meeting these criteria were chosen at random and

invited to participate. Forty-six patients were randomly assigned to either the standard care or the intervention arm. In the standard care group 11/23 patients had type 2 diabetes and 9/23 patients had type 2 diabetes in the intervention group. Baseline characteristics (age, sex, mean duration of diabetes, mean duration of insulin therapy) were not statistically significant between the two groups. Patients in the intervention group averaged three calls per week, each call lasting about 15 minutes. Patients in the intervention group had a significant ($p<0.001$) decline in HbA1c levels (0.096 ± 0.01 to 0.078 ± 0.008) over the 6-month time period of the study. There was no significant change (0.094 ± 0.008 to 0.089 ± 0.010) in the standard group. Over the study period there was a mean weight loss of 4kg in the intervention group and no weight gain in the standard group. The authors note that the intervention was very time consuming and involved a single nurse. However, the patients reported that the key factor for their improvement was the frequent contact by a caring and knowledgeable nurse.

Vallis [103] undertook a study to evaluate the role of disease specific psychosocial factors in differentiating individuals who are strongly adherent from those who are strongly non-adherent to their self care regimen. If psychosocial factors are able to differentiate adherent from non-adherent individuals, clinical interventions to change these factors may improve adherence which may lead to improve metabolic control. Vallis reported that psychiatric morbidity studies generally indicate that people with diabetes or other chronic illness have higher rates of psychiatric disorders or morbidity such as mild depression, anxiety or adjustment disorders than do a similar group of healthy people. The clinical staff (nurse and dietitian) identified a total of 22 individuals, during routine assessment and follow up over a 10 month period, at the Nova Scotia Diabetes Centre. Based on a rating form (14 adherence behaviours assessed), completed by the clinic staff, 15 patients (seven type 1 and eight type 2; 10 females) were classified as strongly non-adherent and seven patients (two type 1 and five type 2; 5 females) were classified as strongly adherent. Adherent participants tended to be older with a mean age of 50.7 years compared to 39.9 years in the non-adherent group. This difference was not statistically significant however age at diagnosis did differ significantly, mean age of the adherent group was 45 years and 29.6 years for the non-adherent group. Thus, the non-adherent group had their disease longer. Based on BMI the adherent group (BMI 23.74) differed significantly from the non-adherent group (BMI 29.39). Furthermore the participants with type 2 diabetes were significantly heavier compared to those participants with type 1 diabetes. Group adherence and non-adherence was validated by comparing HbA1c and self reported adherence (Diabetes Behaviour Questionnaire and the Self-reported Adherence Scale) for each participant. Diabetes specific measures included the diabetes adjustment scale, barriers to adherence questionnaire, health beliefs questionnaire, diabetes family behaviours checklist, and diabetes knowledge and management skills

assessment. The HbA1c value for the adherent group, mean 6.53 ± .38, was significantly lower than for the non-adherent group, mean 9.12 ± 1.38. For the diabetes specific measures three scales, significantly differentiated the two groups:

- the health beliefs questionnaire, perceived benefits of adherence,
- the diabetes adjustment scale, emotional impact of diabetes, and
- the barriers to adherence questionnaire, barriers to diet.

These three factors correctly classified 95% (21/22) of the subjects. One non-adherent participant was classified incorrectly. Non-adherent participants experienced greater negative emotional impact of having diabetes and greater barriers to adhering to a diet, and perceived fewer benefits to adherence. However, adherent participants had lower knowledge scores than non-adherent participants. Age, marital status, diabetes subtype, and duration of diabetes did not alter the results. The author concluded that cognitive (health beliefs), emotional (quality of life) and problem solving (barriers to adherence) issues need to be addressed to improve adherence.

APPENDIX H: QUALITATIVE RESEARCH STUDIES

Table abbreviations

CDA – Canadian Diabetes Association

DE – diabetes education

DEP – diabetes education program

DM – diabetes mellitus

DSM – diabetes self-management

DTRC - Diabetes Treatment and Research Centre

F – females

GP(s) – general practitioner(s)

HC – health care

r(s) – hour(s)

M – males

min. – minute(s)

mo – month(s)

NIDDM – non-insulin dependent diabetes mellitus

OHA – oral hypoglycemic agents

pt(s) – patient(s)

QOL – quality of life

USA – United States of America

wk(s) – week(s)

y(s) – year(s)

Table 5: Qualitative research studies

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Dietrich, 1996 (30)	Purpose: to investigate attitudes of people with diabetes toward their disease and its treatment from their point of view. Research question: "what are the feelings and beliefs of people with NIDDM about diabetes and its treatment?" Included: 7 NIDDM women from a rural hospital in Illinois, USA (aged 37-81 ys; 4/7 on insulin; 5 wks-20 ys length of diabetes), no extra DE other than that routinely given by HC providers Excluded: women with gestational diabetes	Approach: grounded theory Sampling: purposeful sample (support from physicians and a patient educator); saturation achieved Data collection: 7 open-ended interviews set at a time and place of participants' convenience Data analysis: naturalistic content analysis using constant comparison, with continuous, simultaneous collection and processing of data (each interview was transcribed and its content compared to that of other interviews)	The analysis revealed 4 themes: *physician's reaction at diagnosis *perceived seriousness of diabetes *physician-patient relationship *self-care The reaction and attitude physicians displayed at diagnosis were crucial in influencing patients' attitudes toward their diabetes and its treatment. Newly diagnosed patients showed strong motivation with regard to treatment. However, difficulties in adhering to a treatment plan and inadequate perceived seriousness of diseases were factors contributing to a lack of compliance. Participants reported that when complications started their compliance improved.	*good description of audit trail *detailed description of data collection, processing and analysis methods; *no information on length of interviews *lacks theoretical sampling ;saturation mentioned but not clear if it was reached *insufficient description of pts *sample did not include the full range of possible cases: all volunteers females, no males, low level of education, limited geographic area *quotes cited to support a theme; not clear whether investigator searched for negative/deviant cases *findings based on single interviews; triangulation not present *data interpreted only by one investigators *no returning to participants to confirm emerging themes *observer bias is not mentioned/discussed

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Goldman & Maclean, 1998 [49]	Purpose: to further extend the understanding of individuals' experiences of living with diabetes Included: 30 individuals with insulin-requiring diabetes (defined as the need for daily insulin injections) in a large Canadian city, with no major diabetes-related complications, able to converse in English (17F, 13 M; aged 20-76 ys; duration since diagnosis 1-37 ys); The sample was a subset of a larger sample that also included individuals with type 2 diabetes who did not require insulin.	Approach: theory of narrative, using social theory of identity Sampling: purposeful (volunteers recruited through advertising on the radio, local newsletter of CDA, from diabetes clinics and DE programs of 2 university-affiliated hospitals); Data collection: 83 semi-structured interviews (all audiotaped and transcribed); from 2-5 interviews/participant; average length of approx. 1 hour and 45 minutes; probe sheets suggesting topics (identified through literature review) and questions sent out prior to the first interview; Data analysis: narrative analysis (approach significantly influenced by recent psychosocial theory on identity and chronic illness); independent analysis by the 2 authors and repeated consultations with each other to compare findings; themes developed using interpretive observations and grounded in excerpts from transcripts	Themes identified: *diagnosis and identity: diagnosis of diabetes was conceptualized as an assault to personal identity *identity and treatment management: initial disruption was followed by a process of negotiation whereby individuals grappled with identity issues to adapt to the condition and integrate it into their lives; the process was socially shaped and influenced individuals perceptions of their diabetes management *identity and the ongoing nature of adjustment: individuals identities evolved and changed as they encountered new experiences and changed the meaning of diabetes management in relation to these transitions; diabetes-related behaviors changed over time, and vigilance increased or decreased depending on the particular identity needs of the individual	*good description of data collection, processing and analysis methods and audit trail *interviews audiotaped and transcribed but tapes were destroyed following transcription to ensure confidentiality *insufficient description of pts' characteristics *insufficient description of setting *lacks theoretical sampling; saturation not mentioned *quotes cited to support themes; not clear whether negative/deviant cases were searched for independent analysis by two authors but with repeated consultations to compare findings *stories were analyzed using theoretical ideas derived from literature on the sociology of chronic illness *triangulation not clear *themes not reviewed with participants *observer bias not mentioned/discussed *no discussion of limitations

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Handron & Legget-Frazier, 1994 [52]	Purpose: to investigate stressors that impact on ability of NIDDM pts to comply with diabetes self-management Included: 6 NIDDM pts referred to an outpatient DEP, at a large medical school in the Southeast, USA (aged 28-68 ys; 2M/ 4F; 5/6 married; 1/6 widowed 4/6 had children), and their families Excluded: any patient exhibiting severe psychopathology	Approach: grounded theory Sampling: convenience sample (every second pt referred to DEP) Data collection: 2-12 non-structured in-depth interviews (open-ended questions) within context of counseling sessions (free of charge; continued over 4-12 wks based on pt's needs) in an informal setting; detailed notes written immediately after session to record data Data analysis: content analysis (categories emerged from knowledge from literature and from interview notes); 2 investigators reviewed data to validate coding	Themes and problem areas identified: *patients' inner experience with diabetes *family stressors that affect patients with diabetes *coping strategies of type II diabetes patients *psychopathology The factors impacting diabetes management that emerged most often in these patients included a sense of isolation from family members, codependency, experience of loss, secondary stressors not related to diabetes, overuse of defense mechanisms, low-self-esteem irritability, and depression. The ability of health care professionals to identify specific psychosocial stress factors that affect type II diabetes patients and to offer alternative interventions may truly improve the management of their medical regimens.	*good description of data collection, processing and analysis methods and audit trail *lacks theoretical sampling and saturation *interviews not taped but rationale discussed *data recording relies on memory; findings are subject to memory bias *insufficient description of pts *sample not representative for all NIDDM pts *only few quotes cited to support themes; not clear whether negative/deviant cases were searched for *the themes were not validated back with participants *data interpreted by 2 researchers (not clear whether independently) *observer bias not mentioned/discussed *no detailed discussion of limitations

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Ellison & Rayman, 1998 [36]	Purpose: to explore the experience of learning self-management among women of type 2 diabetes Interview questions: "Tell me about your experience of managing your diabetes?", "What do you think makes you a successful manager of your diabetes and at what point did you become a successful manager?", "What does health mean to you?", "How do you differentiate between health and having diabetes?", What do you do to stay healthy?" Included: 17 type 2 DM women (aged 46-69 ys; 13 Caucasians, 2 Native Americans, 1 African-American, 1 Hispanic; mean diabetes duration: 11 ys; 10 on insulin, 5 on OHA, 2 on insulin and OHA; occupations: homemaker, licensed practical nurse, school cafeteria, worker, mental health technician, math paraprofessional; 11 received care at private clinic and 6 received care at an urban public clinic; both clinics associated with DTRC); all completed a DEP and were nominated as exemplars in DSM (no diabetes related hospitalization; HbA1c</=7% in past 12 mo) by DTRC experts, Midwest, USA	Approach: grounded theory Sampling: purposeful sampling Data collection: 4 structured focus group interviews (2-3 hours in length; 3-7 different participants; audiotaped) by 1 investigator, clinical record review, investigator field notes (by the other investigator); Data analysis: constant comparative method keeping in mind initial impressions and insights (diabetes nurse specialists acting as consultants reviewed findings at several points during analytic process and examined and verified congruency between emerging findings and text; typed summaries of results were reviewed by participants for credibility, accuracy and truth)	Major findings: *the illumination of a process of self-management characterized by 3 distinct nonlinear phases: 1) management-as-rules; 2) management-as-work;3) management-as-living *the description of transitional events signaling movement between phases *an active view of management as enabling health and health as pursuing goals. Health care providers need to know as much about the social context of patients' lives – their goals, problems, and dreams – as is known about how they are eating, exercising, and checking blood glucose levels. The challenge for providers is to translate into practice the contextual factors of successful management.	*good description of data collection, processing and analysis methods and audit trail *good description of pts' characteristics *interviews were audiotaped *insufficient description of setting *lacks theoretical sampling; saturation mentioned but not clear if it was achieved *sample did not include all possible cases *some quotations cited to support themes; not clear whether negative/deviant were searched for *findings were reviewed with participants *observer bias is not mentioned/discussed *not clear whether data interpreted by only one or both investigators independently or not *not clear whether the same diabetes nurse specialists reviewed data, independently or not *no detailed discussion of limitations

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Rayman & Ellison, 1998 [85]	Purpose: to investigate women's perspectives of provider and setting factors that support their ability to be effective in type 2 diabetes self-management. Interview question: "What is it about where you get your care that helps you manage the diabetes" Included: 17 type 2 DM women (aged 46-69 ys; 13 Caucasians, 2 Native Americans, 1 African-American, 1 Hispanic; mean diabetes duration: 11 ys; 10 on insulin, 5 on OHA, 2 on insulin and OHA; occupations: homemaker, licensed practical nurse, school cafeteria, worker, mental health technician, math paraprofessional; 11 received care at private clinic and 6 received care at an urban public clinic; both clinics associated with DTRC); all completed a DEP and were nominated as exemplars in DSM (no diabetes related hospitalization; HbA1c</=7% in past 12 mo) by DTRC experts, Midwest, USA	Approach: grounded theory Sampling: purposeful sample Data collection: 4 focus-groups, interviews (3-7 different participants; 2-3 hours in length; audiotaped), clinical records Data analysis: constant comparative method (data collection and analysis took place simultaneously; coding system yielded by preliminary analysis of textual data; at several points during study, emergent findings were reviewed by diabetes nurse specialists acting as consultants who evaluated the fit of data with the coding system; findings also reviewed with participants)	Themes emerged: *turning points facilitated the self-management experience along with certain obstacles and barriers *a culture of caring facilitated learning self-management *significant shifts in patient-provider relationships accompanied a phasic process of learning self-management *a set of personal characteristics most likely influenced the process of learning self-management within the context of the expert care setting The knowledge and skills obtained through diabetes education are essential for initiating the self-management process. However, becoming an effective self-manager requires an organizational culture that supports elements of a role reversal in which patients can be experts and providers can be mentors. Important aspects of self-management that go far beyond knowledge of disease and related psychomotor skills are learnable in the context of caring relationships.	*sampling method not mentioned/described *sufficient description of data collection, processing and analysis methods and good audit trail discussed *good description of setting and pts *interviews were audiotaped *lacks theoretical sampling; saturation not mentioned *the sample did not include all possible cases *findings were reviewed with participants *researchers used 2 different methods of data collection *observer bias is not mentioned/discussed *not clear whether data interpreted by only one or both researchers independently or not *not clear whether the same diabetes nurse specialists reviewed data, independently or not *no detailed discussion of limitations

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Simmons et al. 1998 [89]	Purpose: to identify and quantify barriers to diabetes care perceived by diabetic subjects from a multiethnic, urban community A qualitative approach (anthropological study) was used to define the domain of potential barriers for patients from both patient's and health worker's perspective Included in the anthropological study: 57 diabetic pts and HC providers (mainly New Zealand Europeans, Maori and Pacific Islanders; 25 health workers; 30 diabetic pts or their care givers; 21% males; 47% Europeans, 35% unemployed or retired; diverse range of backgrounds; mean age 50 ys; 31% insulin treated) Included in the household survey: all residents of all households in inner urban South Auckland, New Zealand (with the most socio-economically disadvantaged urban districts in New Zealand) between April '92 and August '95.	Approach: combined qualitative approach (using anthropological study) and quantitative approach (household survey using standardized, open-ended questions, interviews not taped) For the anthropological study: Sampling: purposeful (health workers and diabetic pts selected to ensure a range of age, socio-economic, ethnic groups and health workers to provide a multifaceted view of issues surrounding diabetes care) Data collection: 3 focus-group interviews (group of 3 Maori community/hospital workers; group of 4 GPs; group of 5 European diabetic pts) and 47 single interviews (including 2 of Maori workers in a focus group); all were semi-structured interviews, 45 min. in length, and taped. Data analysis: qualitative computer software package (NUD*IST)	Thirty categories of barriers to diabetes care were generated including patient beliefs, internal and external physical barriers, educational barriers, and psycho-social and psychological barriers. In spite of major differences in culture, acculturation, and socio-economic status, the top 10 barriers to diabetes care (precontemplative, limited range of services, no community based, self factors- motivation, unsatisfactory education, diabetes knowledge, public awareness, community support, personal costs of care, health belief spiritual) were similar between the ethnic groups. The most important barriers were perceiving that the benefits of self-care were outweighed by the disadvantages, lack of community-based services, and the limited range of services available.	*good description of data collection, processing, analysis and validation methods *not clear description of pts; *sample not representative *uses a qualitative computer software package to analyze data *lacks theoretical sampling and saturation *list of patient-identified barriers to diabetes care from the anthropological study was applied to the door-to-door survey data for validation of barrier categories *final consensus on barrier categories obtained by a combined review (independent critique by 2 of the researchers) *the interviews from the household survey were not taped; data is subject to selection bias *the themes were not validated with the participants in the anthropological study *quotes not cited to support or challenge the categories of patient-identified barriers to diabetes care; not clear whether negative/deviant cases were searched for *observer bias not mentioned/discussed *no discussion of limitations of the anthropological study

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Mitchell 1997 [69]	Purpose: to explore the QOL for persons living with diabetes Discussion questions: "Please tell me what life is like for you", "What enhances and diminishes the quality of your life?", "How do your routines and relationships change the quality of your life?, "What do you see in the future with respect to the quality of your life?" Included: 19 diabetes pts (aged 26-73ys; 13M/6F; diabetes duration 2mo-17ys; 4 pts on insulin, 8 pts on OHA, 7 pts on diet and exercise)	Approach: guided by theory of human becoming Sampling: method not mentioned Data collection: audiotaped discussions (30 min.-2hrs long; took place in a private office) Data analysis: descriptive-exploratory analysis (steps outlined in: *"Nursing Research: Qualitative Methods"*) involving dwelling of transcripts, extracting themes, forming a unified description of phenomenon, interpreting and discussing findings in relation to nursing science and general research literature	Four themes indicate that day-to-day life for persons with diabetes include: personal evaluations that fortify self-directedness; rebellious decisions that are both helpful and not helpful; comparisons that strengthen personal resolve; and contemplative moments that help to clarify what is important in life. New understanding about what life is like for persons living with diabetes provides insights for how education and practice can be more innovative and participatory (raises important questions about diabetic protocol, professional expectations for compliance and personal transcendence). The challenge for healthcare professionals is to make a difference – a difference that helps people to find their own strength, to reflect on their choices and consequences of those choices, and to clarify their hopes and plans for creating QOL.	*qualitative approach not clearly defined *sampling method not mentioned/described *insufficient description of setting and pts *good description of data collection, processing, analysis and audit trail *sample not representative for all diabetes pts *lacks theoretical sampling and saturation *triangulation not clear *discussions were audiotaped *the themes were not validated with the participants *quotes cited to support themes; not clear whether negative/deviant cases were searched for *data interpreted by one investigator only *findings compared to findings from other qualitative studies on QOL of persons with diabetes *observer bias not mentioned/discussed *no discussion of limitations

Table 5: Qualitative research studies (cont'd)

Study	Study's purpose and source of data	Study's characteristics	Study's findings and conclusions	Issues of rigor
Anderson et al. 1991 [7]	Purpose: examine the context in which the process of restructuring is located when a woman's life is disrupted by a chronic illness ("to explore the everyday world not in itself but as it is articulated to the social relations of the larger social and economic process") Questions: How women's experiences of illness are organized, how they are determined, and what the social relations are that generate them. Included: Chinese and White women recruited with the help of personnel from selected health care and community agencies: *n=15 Anglo-Canadian women with diabetes (age: 26 yrs and older; type 1 or 2 ; 93.33% on insulin; 6.66% on OHA; all spoke English; 13/15 were born in Canada; 2/15 immigrated from Europe; most with high level of education, in professional or semiprofessional jobs and lived alone or in a nuclear family; 26.66% were homemakers/retired) *n=12 Chinese women (age:35 yrs and older; type 1 or type 2; 50% on insulin; 50% on OHA; 83.33 spoke Cantonese only; 50% with Grade 1-7 education; 41.66% with Garde 8-10 education; 8.33% with university education; 50% in unskilled or skilled blue collar occupations; 8.33% in professional or semiprofessional jobs; most lived in extended families; 41.66% were homemakers/retired)	Approach: "institutional ethnography" Sampling: convenience sampling? (method not mentioned) Data collection: audiotaped discussions guided by an interview schedule (constructed in consultation with 2 health care providers and 1 woman with diabetes; sequential interviews over 2 yrs; each was1-2 hours long; most women interviewed in their homes; interviewing shared among investigators with participation of a Cantonese speaking woman for the first year); tapes transcribed by a typist Data analysis: method not mentioned; data organized with a computer program ("the Ethnograph"); data collection and analysis proceeded simultaneously; topics identified from the transcripts by reviewing each line ; investigators not attempting to tabulate categories but to examine recurrent patterns and processes in women's lifes	The restructuring of life in the face of chronic illness has to be viewed within the total circumstances of the woman's life. The styles of managing illness that are often attributed to "ethnic differences" have also to be understood in terms of class relations in the society, and how the social processes organize the experiencing of illness. It is argued that the trends toward individualizing social problems, and shifting the responsibility for caretaking from the state to the individual, obfuscate the social context of illness, and exclude the socially disadvantaged from adequate health care.	*qualitative approach not clearly defined *good description of data collection, processing, analysis and audit trail (uses a qualitative computer software package to analyze data) *lacks theoretical sampling and saturation *discussions were audiotaped and tapes transcribed *the findings were not validated with the participants *triangulation not present *quotes cited to support themes; not clear whether negative/deviant cases were searched for *not clear whether data interpreted by one investigator only *findings not compared to findings from other qualitative studies on QOL of persons with diabetes *observer bias not mentioned/discussed *some study limitations discussed *representativeness limited by the selection process

Discussion

A critical appraisal of the methodological quality of the qualitative research studies reviewed (see criteria used for critical appraisal in Appendix B and comments in Table 5, Appendix H) identified some issues of rigor which limit the validity and transferability of their findings. Although most of these studies provided a good description of methods for data collection, processing and analysis, only few presented the study population and the setting in sufficient details. From the descriptions provided, it appears that, in most studies, the sample did not include all possible cases of patients with type 2 diabetes. Most studies cited quotes to support their themes but only few validated their findings with the participants. Since none of the studies used theoretical sampling it was not clear whether the investigators searched for negative or deviant cases and how they dealt with them. Triangulation was not present/clear in all studies. None of the investigators discussed the observer bias.

References

1. Diabetes and death. *British Medical Journal* 1998;317.
2. Abourizk NN, O'Connor PJ, Crabtree BF, et al. An outpatient model of integrated diabetes treatment and education: functional, metabolic, and knowledge outcomes. *The Diabetes Educator* 1994;20(5):416-21.
3. Agency for Health Care Policy and Research. Adult-onset diabetes occurs much more often among minorities than whites. *Research Activities* 1997.
4. Ahroni JH. Diabetes education and the primary care provider. *Nurse Practitioner Forum* 1998;9(2):66-67.
5. Albano MG, Jacquermet S, Assal JP. Patient education and diabetes research: a failure! Going beyond the empirical approaches. *Acta Diabetologica* 1998;35:207-14.
6. American Diabetes Associates. Position Statement. Implications of the diabetes control and complications trial. *http://www.tpsmedical.com/adaposstate.html* 1993.
7. Anderson JM, Blue C, Lau A. Women's perspectives on chronic illness: ethnicity, ideology and restructuring of life. *Social Science and Medicine* 1991;33(2):101-11.
8. Arnold P, Stepka-Tracey C, Zheng D, et al. Diabetes patient education. *The Journal of the South Carolina Medical Association* 1998;(November):478-84.
9. Barcelo A. Monograph series on aging-related diseases: non-insulin-dependent Diabetes Mellitus. *Health Canada, Health Protection Branch* 1996:17(1).
10. Basa RP, McLeod B. Evaluation of a diabetes specialty centre: structure, process and outcome. *Patient Education and Counseling* 1995;25:23-29.
11. Belton A. Outcome Measurement [Guest Editorial}. *Diabetes Educator* 1998;13.
12. Boehm S, Schlenk EA, Funnell MM, et al. Predictors of adherence to nutrition recommendations in people with non-insulin-dependent diabetes mellitus. *The Diabetes Educator* 1997;23(2):157-65.
13. Boehm S, Schlenk EA, Raleigh E, et al. Behavioral analysis and behavioral strategies to improve self-management of Type II diabetes. *Clinical Nursing Research* 1993;2(3):327-44.
14. Bonnet C, Gagnayre R, d'Ivernois J. Learning difficulties of diabetic patients: a survey of educators. *Patient Education and Counseling* 1998;35:139-47.

15. Brennan A. Diabetes mellitus: biomedical health education/promotion approach. *Diabetic Nursing* 1996;5(17):1060-64.

16. British Medical Journal. Diabetes: a time of excitement - and concern [editorial]. *British Medical Journal* 1998;317:691-92.

17. Brown F. An alternative education. *Nursing Standard* 1991;17(Suppl 5): 54-55.

18. Brown SA. Effects of educational interventions in diabetes care: a meta analysis of findings. *Nursing Research* 1988;37(4):223-30.

19. Brown SA. Studies of educational interventions and outcomes in diabetic adults: a meta analysis revisited. *Patient Education and Counseling* 1990;16:189-215.

20. Brown SA. Meta analysis of diabetes patient education research: variations in intervention effects across studies. *Research in Nursing & Health* 1992;15:409-19.

21. Butler RN, Rubenstein AH, Gracia AMG, et al. Type 2 diabetes: patient education and home blood glucose monitoring. *Geriatrics* 1998;53(5):60-67.

22. Byrne CD. Diabetes care needs evidence based interventions to reduce risk of vascular disease [Editorial]. *British Medical Journal* 2000;320:1554-57.

23. Campbell EM, Redman S, Moffitt PS, et al. The relative effectiveness of educational and behavioral instruction programs for patients with non-insulin dependent diabetes mellitus: A randomized trial. *The Diabetes Educator* 1996;22(4):379-86.

24. Canadian Diabetes Association National Office. *http://www.diabetes.ca* 2000.

25. Chaisson J. Primary prevention of Type 2 diabetes mellitus. *The Canadian Journal of Continuing Medical Education* 1999;(July):85-92.

26. Clement S. Diabetes self-management education. *Diabetes Care* 1995;18(8):1204-14.

27. Colagiuri R, Colagiuri S, Naidu V. Can patients set their own educational priorities? *Diabetes Research and Clinical Practice* 1995;30:131-36.

28. de Lissovoy G, Ganoczy DA, Ray NF. Relationship of Hemoglobin A1c, age of diabetes diagnosis, and ethnicity to clinical outcomes and medical costs in a computer-simulated cohort of persons with Type 2 diabetes. *The American Journal of Managed Care* 2000;6(5):573-84.

29. de Sonnaville JJJ, Bouma M, Colly LP, et al. Sustained good glycaemic control in NIDDM patients by implementation of structured care in general practice: 2-year follow-up study. *Diabetologia* 1997;40:1334-40.

30. Dietrich UC. Factors influencing the attitudes held by women with type II diabetes: a qualitative study. *Patient Education and Counseling* 1996;29:13-23.

31. Domenech MI, Assad D, Mazzei ME, et al. Evaluation of the effectiveness of an ambulatory teaching/treatment programme for non-insulin dependent (type 2) diabetic patients. *Acta Diabetologica* 1995;32:143-47.

32. Duchin SP, Brown SA. Patients should participate in designing diabetes educational content. *Patient Education and Counseling* 1990;16:255-67.

33. Dufton B. Barriers to diabetes self-care. *Beta Release* 1992;16(4):119-25.

34. Dunn SM. Rethinking the models and modes of diabetes education. *Patient Education and Counseling* 1990;16:281-86.

35. Eiser C, Tooke JE. Quality-of-life evaluation in diabetes. *PharmacoEconomics* 1993;4(2):85-91.

36. Ellison GC, Rayman KM. Exemplars' experience of self-managing Type 2 diabetes. *The Diabetes Educator* 1998;24(3):325-30.

37. Fiala J, Gaizauskas D. Healthy weight: a community hospital weight loss program for people with diabetes. *Canadian Journal of Diabetes Care* 1994;18(1):9-15.

38. Fisher L, Chesla CA, Bartz RJ, et al. The family and Type 2 diabetes: a framework for intervention. *The Diabetes Educator* 1998;24(5):599-607.

39. Funnell MM, Anderson RM, Arnold MS, et al. Empowerment: an idea whose time has come in diabetes education. *Beta Release* 1992;16(2):54-58.

40. Funnell MM, Haas LB. National standards for diabetes self-management education programs: a technical review. *Diabetes Care* 1995;18:100-16.

41. Garay-Sevilla ME, Malacara JM, Gutierrez-Roa A, et al. Denial of disease in Type 2 diabetes mellitus: its influence on metabolic control and associated factors. *British Diabetic Association* 1999;16:238-44.

42. Gearhart JG, Forbes RC. Initial management of the patient with newly diagnosed diabetes. *American Family Physician* 1995;51(8):1953-62.

43. Genev NM, Flack JR, Hoskins PL, et al. Diabetes education: whose priorities are met? *Diabetes Educational Priorities* 1991;475-79.

44. Gerstein HC, Meltzer S. Preventive medicine in people at high risk for chronic disease: the value of identifying and treating diabetes. *Canadian Medical Association Journal* 1999;160(11):1593-96.

45. Glasgow RE, Eakin EG, Toobert DJ. How generalizable are the results of diabetes self-management research? The impact of participation and attrition. *The Diabetes Educator* 1996;22(6):573-85.

46. Glasgow RE, La Chance PA, Toobert DJ, et al. Long term effects and costs of brief behavioural dietary intervention for patients with diabetes delivered from the medical office. *Patient Education and Counseling* 1997;32:175-84.

47. Glasgow RE, Osteen VL. Evaluating diabetes education. *Diabetes Care* 1992;15(10):1423-32.

48. Glasgow RE, Ruggiero L, Eakin EG, et al. Quality of life and associated characteristics in a large national sample of adults with diabetes. *Diabetes Care* 1997;20(4):562-67.

49. Goldman JB, MacLean HM. The significance of identity in the adjustment to diabetes among insulin users. *The Diabetes Educator* 1998;24(6):741-48.

50. Greene DS, Beaudin BP, Bryan MJM. Addressing attitudes during diabetes education: suggestions from adult education. *The Diabetes Educator* 1990;17(6):470-74.

51. Greenhalgh T. How to read a paper. Papers that summarise other papers (systematic reviews and meta analyses). *British Medical Journal* 1997;315:672-75.

52. Handron DS, Leggett-Frazier NK. Utilizing content analysis of counseling sessions to identify psychosocial stressors among patients with Type II diabetes. *The Diabetes Educator* 1994;20(6):515-20.

53. Hanefeld M, Fischer S, Schmechel H, et al. Diabetes Intervention Study. Mult-intervention trial in newly diagnosed non-insulin dependent diabetes mellitus. *Diabetes Care* 1991;14(4):308-17.

54. Hartman TJ, McCarthy PR, Park RJ, et al. Focus group responses of potential participants in a nutrition education program for individuals with limited literacy skills. *Journal of the American Diatetic Association* 1994;94(7):744-48.

55. Health Canada. Diabetes in Canada - national statistics and opportunities for improved surveillance, prevention and control. *Health Canada, Health Protection Branch* 2000.

56. Hendricks LE, Hendricks RT. Greatest fears of Type 1 and Type 2 patients about having diabetes: implications for diabetes educators. *The Diabetes Educator* 1998;24(2):168-73.

57. Jacobson AM, de Groot M, Samson JA. The evaluation of two measures of quality of life in patients with Type I and Type II diabetes. *Diabetes Care* 1994;17(4):267-74.

58. Johnson JA. Self-efficacy theory as a framework for community pharmacy-based diabetes education programs. *The Diabetes Educator* 1996;22(3):237-41.

59. Kicklighter JR, Stein MA. Factors influencing diabetic clients' ability to read and comprehend printed diabetic diet material. *The Diabetes Educator* 1993;19(1):40-46.

60. Klepac MJ. Theory and practical applications of a wellness perspective in diabetes education. *The Diabetes Educator* 1996;22(3):225-29.

61. Krishna S, Balas EA, Spencer DC, et al. Clinical trials of interactive computerized patient education: implications for family practice. *The Journal of Family Practice* 1997;45(1):25-33.

62. Leese B. Diabetes Mellitus and the St. Vincent Declaration. The economic implications. *PharmacoEconomics* 1995;7(4):292-307.

63. Lutfey KE, Wishner WJ. Beyond "compliance" is "adherence". *Diabetes Care* 1999;22(4):635-39.

64. Maldonato A, Bloise D, Ceci M, et al. Diabetes mellitus: lessons from patient education. *Patient Education and Counseling* 1995;26:57-66.

65. Maryniuk MD. Measuring outcomes in diabetes care and education. *Diabetes Spectrum* 1996;9(4):260-62.

66. Mayes N, Pope C. Assessing quality in qualitative research. *British Medical Journal* 2000;320:50-52.

67. McLeod B. Research in diabetes education: where have we been and where do we need to go? *Canadian Journal of Diabetes Care* 1998;22(2):20-28.

68. Mickus S, Quaile B. Client management and knowledge outcomes of a diabetes education program. *Canadian Journal of Diabetes Care* 1997;21(3):14-18.

69. Mitchell GJ. Living with diabetes: how understanding expands theory for professional practice. *Canadian Journal of Diabetes Care* 1998;22(1):30-37.

70. Morse J, Field P. *Qualitative research methods for health professionals*. 1995:2nd ed. London: Sage.

71. Mulcahy K. Outcomes-driven diabetes education. *The Diabetes Educator* 1999;25(3):300.

72. Murphy E, Dingwall R, Greatbatch D, et al. Qualitative research methods in health technology assessment: A review of the literature. *Health Technology Assessment* 1998;2(16):277.

73. NHS Centre for Reviews and Dissemination. Promotion of self-management. *Effective Health Care* 2000;6(1):9.

74. Nicolucci A, Cavaliere D, Scorpiglione N, et al. A comprehensive assessment of the avoidability of long-term complications of diabetes. *Diabetes Care* 1996;19(9):927-33.

75. Norman J. Education - a lifelong process. *The Diabetes Educator* 1998;24(2):115-16.

76. Nurymberg K, Kreitler S, Weissler K. The cognitive orientation of compliance of short- and long-term type 2 diabetic patients. *Patient Education and Counseling* 1996;29:25-39.

77. O'Rahilly S, Savill J. Science, medicine, and the future non-insulin dependent diabetes mellitus: the gathering storm. *British Medical Journal* 1997;314(7085):955-64.

78. Overland JE, Hoskins PL, McGill DKY. Low literacy: a problem of diabetes education. *Diabetic Medicine* 1993;10:847-50.

79. Padgett D, Mumford E, Hynes M, et al. Meta analysis of the effects of educational and psychosocial interventions on management of diabetes mellitus. *Journal of Clinical Epidemiology* 1988;41(10):1007-30.

80. Perkins J. How much should we tell them: Patient education for people with diabetes. *Diabetic Complications* 1992;8(2):130-33.

81. Peters AL, Davidson MB. Application of a diabetes managed care program. The feasibility of using nurses and a computer system to provide effective care. *Diabetes Care* 1998;21(7):1037-43.

82. Peyrot M, Rubin RR. Modeling the effect of diabetes education on glycemic control. *The Diabetes Educator* 1994;20(2):143-48.

83. Pichert JW. Improving the impact of diabetes education: a research challenge. *Beta Release* 1990;14(1):7-12.

84. Quackenbush PA, Brown SA, Duchin SP. The influence of demographic and treatment variables on the health beliefs of adults with diabetes. *The Diabetes Educator* 1996;22(3):231-36.

85. Rayman KM, Ellison GC. When management works: an organizational culture that facilitates learning to self-manage Type 2 diabetes. *The Diabetes Educator* 1998;24(5):612-17.

86. Rubin RR, Peyrot M. Men and diabetes: psychosocial and behavioral issues. *Diabetes Spectrum* 1998;11(2):81-87.

87. Saunders JT, Pastors JG. Professional issues in facilitating lifestyle change for people with Type 2 diabetes. *Diabetes Spectrum* 1999;12(1):17-38.

88. Scheen AJ, Lefebvre PJ. [Lessons from the "United Kingdom Prospective Diabetes Study"]. *Revue Medicale de Liege* 1998:53(9):576-78.

89. Simmons D, Weblemoe T, Voyle J, et al. Personal barriers to diabetes care: lessons from a multi-ethnic community in New Zealand. *Diabetic Medicine* 1998;15(959):964.

90. Stam DM, Graham JP. Important aspects of self-management education in patients with diabetes. *Pharmacy Practice Management Quarterly* 1997;17(2):12-25.

91. Steno Diabetes Centre. Is fasting glucose sufficient to define diabetes? Epidemiological data from 20 European studies. *Diabetologia* 1999;42:647-54.

92. Swift CS, Armstrong JE, Beerman KA, et al. Attitudes and beliefs about exercise among persons with non-insulin-dependent diabetes. *The Diabetes Educator* 1995;21(6):533-40.

93. Tan MH. Patient education in management of diabetes mellitus. *The Nova Scotia Medical Journal* 1990;June:91-94.

94. Thompson DM, Kozak SE, Sheps S. Insulin adjustment by a diabetes nurse educator improves glucose control in insulin-requiring diabetic patients: a randomized trial. *Canadian Medical Association Journal* 1999;161(8):959-62.

95. Tildesley HD, Mair K, Sharpe J, et al. Diabetes teaching - outcome analysis. *Patient Education and Counseling* 1996;29:59-65.

96. Tillotson LM, Smith S. Locus of control, social support, and adherence to the diabetes regimen. *The Diabetes Educator* 1996;2(2):133-39.

97. Tilly KF, Belton AB, McLachlan JFC. Continuous monitoring of health status outcomes: experience with a diabetes education program. *The Diabetes Educator* 1995;21(5):413-19.

98. Travis T. Patient perceptions of factors that affect adherence to dietary regimens for diabetes mellitus. *The Diabetes Educator* 1997;23(2):152-56.

99. Tu KS, Morrison E. Diabetes self-care practices, barriers, and outcomes in an Indigent population: an exploratory study. *Journal of Nursing Science* 1996;1(3-4):88-98.

100. U.K. Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. *Lancet* 1998;352(9131):837-53.

101. U.K. Prospective Diabetes Study Group. Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes. *British Medical Journal* 1998;317(7160):703-20.

102. U.K. Prospective Diabetes Study Group. Quality of life in Type 2 diabetic patients is affected by complications but not by intensive policies to improve blood glucose or blood pressure control. *Diabetes Care* 1999;22:1125-36.

103. Vallis TM. Understanding diabetes nonadherence: psychosocial factors associated with poor self-care. *Canadian Journal of Diabetes Care* 1997;22(4):13-21.

104. Vierenga ME, Wuethrich KL. Diabetes program attrition: differences between two cultural groups. *Health Values* 1995;19(3):12-21.

105. Vijan S, Stevens DL, Herman WH, et al. Screening, prevention, counseling, and treatment for the complications of Type II Diabetes Mellitus. *JGIM* 1997;12:567-80.

106. Wang CY, Fenske MM. Self-care of adults with non-insulin-dependent diabetes mellitus: influence of family and friends. *The Diabetes Educator* 1996;22(5):465-70.